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The Efficacy of Amniotic Versus Collagen Membrane in Immediate Dental Implant Augmented with Osteon™ II Collagen Bone Graft

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ABSTRACT

Background: Dental implants are the most common solution for missing teeth, achieving osseointegration through a direct bond with living bone.

Purpose: This study aimed to assess the effectiveness of amniotic membrane versus collagen membrane in immediate dental implant augmented with osteon™ II collagen bone graft in a follow up to 9 months by clinical and radiographic parameters.

Methods: This research has been designed as a randomized controlled clinical study. Cases have been divided randomly into 2 equal groups by flip coin. Group I included cases that were treated with immediate implant augmented by Osteon™ II collagen bone graft with collagen membrane. Group II included patients that were treated with immediate implant augmented by Osteon™ II collagen bone graft with amniotic membrane.

Results: A statistically insignificant variance was discovered in clinical and radiographic parameters at different intervals. There was an improvement in marginal bone level, bone density, and marginal bone loss in both groups gradually, but no change in implant stability, mPI, MGI, and PP.

Conclusion: The use of amniotic or collagen membrane combined with Osteon™ II collagen bone graft appeared to improve bone density and implant stability and maintain bone level around immediately placed dental implant during the observation period of the study. The use of amniotic membrane seemed to produce comparable clinical and radiographic results to collagen membrane in Guided Bone Regeneration (GBR) around immediate dental implant.

Keywords: Collagen membrane, Amniotic, Osteon™ II, Dental, Implant.

INTRODUCTION

Dental implants are presently the most common method for replacing missing teeth. As a direct structural and functional connection between organized living bone and the surface, this integration is referred to as osseointegration [(1)].

Immediate implants have gained widespread acceptance regardless of their controversial beginnings, and the current research regularly indicates excellent outcomes (Averaging from ninety-four to one hundred). They offer clinically apparent advantages. The surgical requirements for immediate implantation involve extraction with minimal trauma, preservation of the extraction socket walls, and thorough alveolar curettage to remove all pathological material. Primary stability is a critical necessity, attained by positioning an implant that surpasses the alveolar apex by three to five millimeter, or by utilizing an implant with a diameter higher than that of the residual alveolus. Esthetic emergence in the anterior region is attained through sub-crest implantation of one to three millimeters. The disadvantages include significant controversy surrounding the optimal modality for treating marginal voids, the extra costs related to grafting and barrier membrane usage eliminate the perceived cost benefits from fewer operations, more extensive soft tissue manipulation is necessary for the submerged healing protocol in immediate implants, and the surgery might additionally be technically more challenging [(2)].

Several approaches, included flapless protocols, connective tissue grafting, instant provisionalization, techniques (Guided bone regeneration), and the gap is filled with a bone replacement graft, have been proposed to improve the cosmetic results and prevent bone dimensional alterations [(3)].

Osteon™ II is an alloplastic material that is seventy percent hydroxyapatite and thirty percent beta tricalcium phosphate that are the most similar mineral components to those found in human bone. It is an osteoconductive material that functions as a scaffold for bone growth. It demonstrates a porosity structure that is interconnected and comparable to that of human cancellous bone. For facilitating the manipulation and shaping of Osteon™ II throughout the procedure of grafts and to enhance its osteoconductivity, collagen may be incorporated into Osteon™ II. For example, Osteon™ II collagen consists of bovine type I collagen and synthetic bone graft [(4)].

Absorbable GBR membranes were developed and prepared using collagen. Nevertheless, it has several disadvantages, such as a high solubility in common dilute acid solutions and poor mechanical strength. The membrane's mechanical characteristics, especially its optimal space maintenance and stability, are crucial for the prevention of fibroblast cell ingrowth and the support of the development of new bones [(5)].

Amniotic membrane is a membrane that originated from innermost layer of human fetal membrane. This membrane has useful properties as biomaterial in dentistry this membrane has

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immunomodulatory properties. Amnion membrane has growth factor that induce angiogenesis and epithelization in dentistry [6]. Therefore, the goal of present research was to assess the effectiveness of amniotic membrane versus collagen membrane within immediate dental implant augmented with osteon™ II collagen bone graft in a follow up to 9 months by clinical and radiographic parameters.

PATIENTS AND METHODS

Study design and settings: This investigation was conducted as a randomized controlled clinical study and involved eighteen cases of both sexes. Cases' age varied between twenty and fifty years, with eight men and ten women. All cases were chosen from the Outpatient Clinic of Oral Medicine, Periodontology, Oral Diagnosis, and Dental Radiology at the Faculty of Dental Medicine Al-Azhar University, Assiut Branch. All selected cases had hopeless teeth assessed by clinical and radiographic examination need for extraction and referred to immediate dental implant placement.

Inclusion criteria: All cases ought to be free from systemic illnesses according to the American Dental Academy's general guidelines for referring dental patients to specialists and other care settings [7]. Cases must be supportive, maintain good oral hygiene**,** and motivated. The implant sites ought to have opposing natural teeth that are neither drifted, malposed, nor over-erupted relative to the implant site. Additionally, the implant sites must possess adequate vertical inter-arch space to accommodate restorative components, in addition to adequate bone quantity (Height and width) and suitable quality of bone.

Exclusion criteria: Acute infected socket and any socket with wall defect, patients who had para functional habits involved clenching and bruxism, heavy smokers, alcohol or drug abused patients, uncontrolled periodontal conditions or oral diseases, and past of radiotherapy in neck and head region.

Patient grouping and randomization: Cases have been divided randomly into 2 equal groups by flip coin. Group I: Included 9 cases that were treated with immediate implant augmented by Osteon™ II collagen bone graft with collagen membrane (Figure 1 & 2) and group II: Included 9 patients who were treated with immediate implant augmented by Osteon™ II collagen bone graft with amniotic membrane (Figure1 & 3).

Clinical evaluation: The subsequent clinical variables have been utilized and documented prior to and following implants at baseline, three, six-, and nine-months post-surgery: Modified plaque index (mPI) [8], peri-implant probing depth (PPD), implant stability, and modified gingival index (mGI). All implants were assessed for primary stability implant -insertion using an Osstell® Mentor device, which utilizes resonance frequency analysis to evaluate implant stability. Further resonance frequency analysis (RFA) was conducted at the six-month monitoring to assess secondary stability.

Radiographic evaluation: Marginal bone level and bone density. Bone density around the implant was evaluated using cone-beam computed tomography that were engaged pre-operatively, as well as at 3, 6 & 9 months postoperatively to assess bone density around dental implants.

Ethical approval: The research protocol received approval from the Ethical Committee of the Faculty of Dental Medicine at Al-Azhar University, Assiut Branch, under the designation (AUAREC2023011-2). All cases were comprehensively informed about the nature, potential hazards, and advantages of their participation in this investigation and signed their informed consent forms.

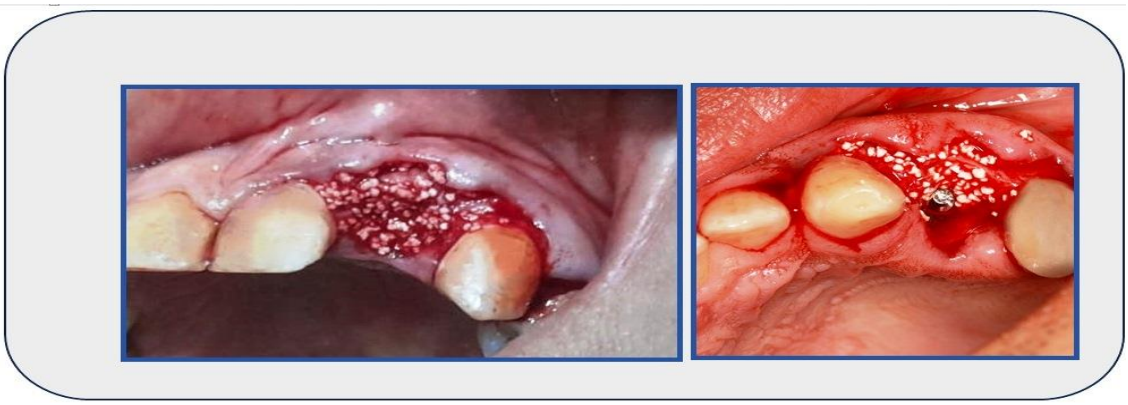

Figure (1): Clinical photograph of applied bone graft around implant site.

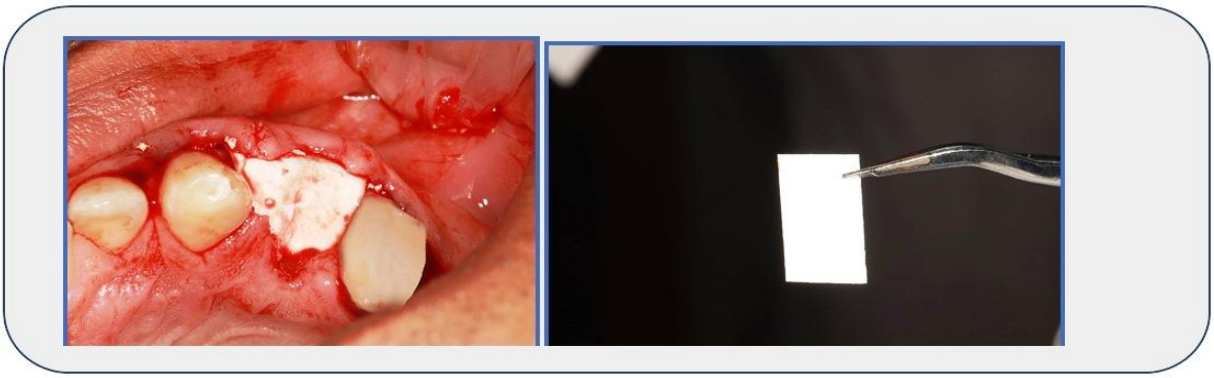

Figure (2): Clinical photograph of collagen membrane cover the implant site in G.

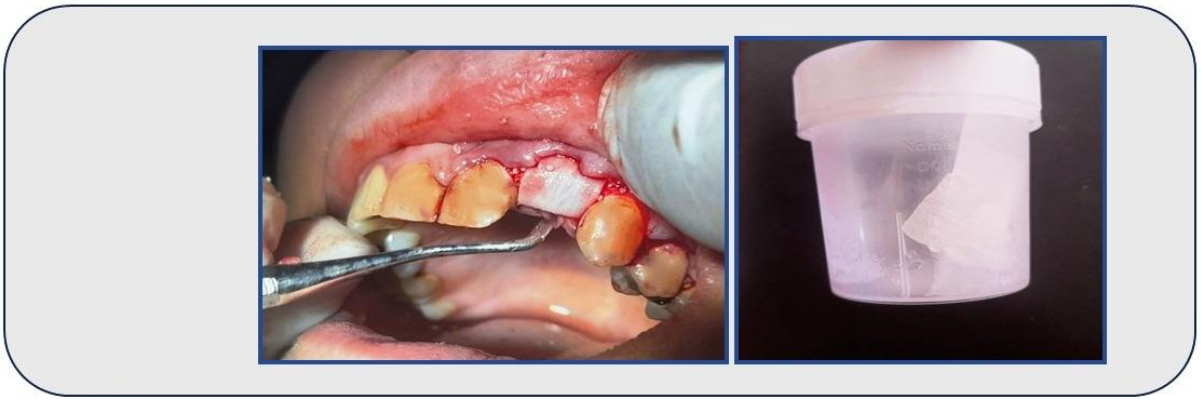

Figure (3): Clinical photograph of Amniotic membrane cover the Bone graft in G.

Statistical Analysis

The standard deviation and mean have been computed for each group in every test. The information has been assessed for normality utilizing the Kolmogorov-Smirnov and Shapiro-Wilk tests, revealing a non-parametric (non-normal) distribution. The Mann-Whitney test has been utilized for comparing 2 groups in independent samples. The Wilcoxon test has been utilized for comparing two groups within associated samples. Spearman correlation was utilized to determine the relationship among various variables, with the significance threshold established at P-value ≤ 0.05 or equal. Statistical analysis was conducted using IBM® SPSS® Statistics Version 20 for Windows.

RESULTS

This research involved eighteen cases, comprising eight men and ten women, aged between twenty and fifty years, with a mean age of 33.72 ± 8.55, who presented with hopeless teeth designated for extraction and subsequent immediate dental implant placement.

Regarding marginal bone loss and bone density: A statistically significant variance observed among the baseline and each interval in every group. A statistically insignificant variance at baseline, three months, six months, and nine weeks among group II & group I.

Regarding implant stability, mPI, mGI and PPD: A statistically significant increase was observed among baseline and six weeks in groups I and II. A statistically insignificant difference was observed at baseline and at six weeks among group II & group I. **For bone loss correlation results**, there was positive correlation with all parameters except with bone level, which showed negative correlation. The strongest correlation was found with bone level, while nearly no correlation was found with mPI.

For bone density correlation results, there was positive correlation with all parameters except with bone level, which showed negative correlation. The strongest correlation was found with implant stability, while nearly no correlation was found with mPI. **For implant stability**, there was positive correlation with all parameters except with bone level, which showed negative correlation. The strongest correlation was found with bone density, while weakest correlation was found with PPD. **For mPI**, there was positive correlation with all parameters except with bone loss, which showed negative correlation. The strongest correlation was found with PPD, while weakest correlation was found with bone loss.

For mGI, there was positive correlation with all parameters except with bone level, which showed negative correlation. The strongest correlation was found with bone level, while weakest correlation was found with bone loss. **For PPD**, there was positive correlation with all parameters except with bone level, which showed negative correlation. The strongest correlation was found with bone loss while weakest correlation was found with implant stability (Table1).

Table (1): The means ± standard deviation (SD) and p-values of different parameters

			Baseline	After 3m	After 6m	After 9m	p-value
Marginal Bone loss	**Group I**	Mean	0.00	0.28	0.53	0.80	**<0.001***
		Standard Deviation	0.00	0.17	0.24	0.21	
		Min	0.00	0.20	0.30	0.50	
		Max	0.00	0.50	1.00	1.20	
	Group II	Mean	0.00	0.24	0.49	0.81	**<0.001***
		SD	0.00	0.15	0.18	0.13	
		Min	0.00	0.00	0.20	0.60	
		Max	0.00	0.50	0.80	1.00	
Bone density	**Group I**	Mean	521.11	726.67	716.11	705.56	**<0.001***
		SD	15.37	14.14	18.33	18.78	
		Min	500.00	710.00	690.00	680.00	
		Max	540.00	750.00	750.00	740.00	
	Group II	Mean	525.00	734.33	723.33	715.56	**<0.001***
		SD	19.69	14.46	11.99	8.82	
		Min	500.00	710.00	700.00	700.00	
		Max	550.00	750.00	735.00	730.00	
Implant stability	**Group I**	Mean	74.22		87.67		**0.008***
		SD	3.87		2.60		
		Min	69.00		84.00		
		Max	80.00		92.00		
	Group II	Mean	76.56		89.22		**0.007***
		SD	4.93		1.92		
		Min	68.00		86.00		
		Max	83.00		92.00		
mPI	**Group I**	Mean			0.44	0.56	**0.317ns**
		Standard Deviation			0.53	0.53	
		Min			0.00	0.00	
		Max			1.00	1.00	
	Group II	Mean			0.44	0.56	**0.317ns**
		Standard Deviation			0.53	0.53	
		Min			0.00	0.00	
		Max			1.00	1.00	
mGI	**Group I**	Mean			0.44	0.78	**0.180ns**
		Standard Deviation			0.53	0.44	
		Min			0.00	0.00	
		Max			1.00	1.00	
	Group II	Mean			0.33	0.67	**0.083ns**
		Standard Deviation			0.50	0.50	
		Min			0.00	0.00	
		Max			1.00	1.00	
PPD	**Group I**	Mean			1.61	1.75	**0.059ns**
		SD			0.55	0.52	
		Min			1.00	1.25	
		Max			2.50	2.75	
	Group II	Mean			1.50	1.61	**0.102ns**
		SD			0.18	0.13	
		Min			1.25	1.50	
		Max			1.75	1.76	

DISCUSSION

Amniotic membrane is a membrane that originated from innermost layer of human fetal membrane. This membrane has immunomodulatory properties and factor that facilitate epithelialization & angiogenesis in dentistry. This material contains antimicrobial characteristics against various pathogenic microbes in the oral cavity [9, 10].

The present work can be considered as novel research comparing with collagen membrane, amniotic membrane hasn't affected on bone density and implant stability or preservation of marginal bone level during the different interval periods. It reported statistically significant leads to both groups at the different observational periods if comparing with the base line. The greater average of bone density, quality and level around dental implant is referred to as the bone grafting material. Alloplastic bone grafting materials cause OSTEON™ II collagen through osteoconduction. The host osteoprogenitor and angiogenic cells utilize graft as a scaffold to produce new bone across the jumping space. Because the host cells differentiate and mature in graft, a functional skeletal network forms and supplants the graft via a process of "creeping substitution" [11, 12].

Although GBR therapy with collagen membranes promotes bone regeneration, involving increases in bone height, new bone-to-implant contact, and bone fill, these effects are observed at a later stage of healing. In contrast, human amnion membranes were identified as a suitable platform for enabling osteogenic differentiation. The acellular human amnion membranes demonstrated the ability to facilitate rapid wound healing and promote bone induction. This may be attributed to its composition of growth factors, fibronectin, and laminin that collectively offer an appropriate substrate for bone induction. This substrate facilitated the induction of progenitor and/or stem cells in the operating area in osteoblasts via its growth factor content, thereby promoting the growth of new bones [13-15].

As regards the marginal bone level, the accepted guidelines for implant induced bone loss are below 1.5 millimetre for the 1st year after implant loading and below 0.2 millimetre annually [16, 17]. The means of marginal bone loss recorded in both groups (0.80 ± 0.21 and 0.81± 0.13 mm) after 9 months, were within the accepted limits occurring with adequate osseointegration. It may be due to proper patient and implant selection, proper surgical protocol and adequate loading of the implant prosthesis.

The stability of the implant can be evaluated clinically by measuring the insertion torque value or through resonance frequency analysis. Insertion torque measurement is a recognized technique. Nevertheless, it can evaluate only the primary stability throughout implant insertion. Resonance frequency analysis can be utilized at any point throughout implant life [18]. The documented ISQ levels for effectively integrating implants following one year vary between fifty-seven and eighty-two, with a mean ISQ of 69 [19] . The current results illustrated that the mean values of primary and secondary stability were 74.22 ± 3.87 and 87.67 for group I and 76.56 ± 4.93 and 89.22 ± 1.92 for group II respectively, which were within the accepted levels and consistent with studies stated that stability of implant with ISQ above sixty-two is regarded appropriate [20, 21]. A statistically significant variance was discovered among secondary and primary stability within the two groups with insignificant variance among both groups. These results disagree with authors who observed significant rise in bone deposition within cases managed with human amniotic membrane that has bio-potential osteogenic and adipogenic differentiation due to its high content of mesenchymal stem cells [22].

A statistically insignificant variance was discovered in both mPI and mGI between the use of collagen or amniotic, membrane as a coverage over the grafting bone substitute around the dental implant as the use of the resorbable membrane provided haemostatic function, facilitating semi permeability, natural enzymatic degradation, early wound stabilization, chemotactic ability to attract fibroblasts, and allowed nutrient passage [23].

Regarding PPD in the current investigation, the means after 9 months were 1.75 ± 0.52 and 1.61± 0.13 within group I and II correspondingly with statistically insignificant variance was discovered among both groups. Successful implants typically permit probe penetration of about three millimeters following implant loading, assessed from crown margin to sulcus base [24].

Within the current research, a correlation between marginal bone loss & clinical parameters was reported. This is contradictory to findings of different studies reported that non-invasive clinical examinations demonstrated a poor association with radiographic evaluations of peri-implant bone loss. The relationship among interproximal probing depth and bone loss remains unknown [25, 26].

Finally, more longitudinal studies are needed and should be conducted to elucidate the role of amniotic membrane versus collagen membranes around immediate dental implant.

CONCLUSION

The use of amniotic or collagen membrane combined with Osteon™ II collagen bone graft appeared to improve implant stability, bone density and maintain bone level around immediately placed dental

implant during the observation period of the study. The use of amniotic membrane seemed to produce comparable clinical and radiographic results to collagen membrane in GBR around immediate dental implant.

DECLARATIONS

- **Consent for publication:** I certify that each author has granted permission for the work to be submitted.
- **Funding:** No fund.
- **Availability of data and material:** Available.
- **Conflicts of interest:** None.
- **Competing interests:** None.

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