

Efficacy of Mixture of Osteon II Collagen with Hyaluronic Acid for Immediate Implant Placement in Chronic Infected Socket (Clinical and Radiographic Study)

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Abstract

Objective: This randomized controlled trial (RCT) was conducted to compare the effectiveness of Osteon II collagen with hyaluronic acid versus Osteon II collagen alone for immediate implant placement in infected sockets. **Patients and Methods:** This study was conducted on 20 patients at the Department of Oral and Maxillofacial Surgery at Al-Azhar University's Assiut Branch and they were divided into; Group I (control): 10 patients who received immediate dental implants with Osteon II collagen graft only and Group II: 10 patients who received immediate dental implants with Osteon II collagen with Hyaluronic acid graft. **Results:** Regarding Modified Bleeding Index (MBI), there was no statistically significant difference between 6 months and 9 months in Group I, while there was a statistically significant difference in Group II. There was no statistically significant difference at 6 months and 9 months between Group I and Group II. Regarding marginal bone loss (MBL), in Group I, there was a statistically significant difference between baseline, 3 months and 6 months. In Group II, there was a statistically significant difference between baseline, 3 months and 6 months. There was no statistically significant difference at baseline and 3 months between Group I and Group II. There was a statistically significant difference at 6 months between Group I and Group II. **Conclusion:** Adding hyaluronic acid to Osteon II Collagen contributes to increased bone density, improved implant stability, a reduction in MBL, and a shorter healing time.

Keywords

Osteon II, Hyaluronic Acid, Immediate, Implant, Bone

1. Introduction

Dental implant therapy has transformed how dentistry is currently carried out and is regarded as the “gold standard” for the rehabilitation of edentulous areas. Patients demand quick delivery of implant-supported restorations and minimally invasive procedures [1].

Simplified surgical procedures, quicker treatment times, optimal three-dimensional implant location, presumed preservation of alveolar bone adjacent to tooth extraction, and soft tissue aesthetics are all benefits of immediate implants that outweigh those of delayed ones [2].

The presence of periapical pathology, the absence of keratinized tissue, the thin tissue biotype, and the lack of complete soft tissue closure over the extraction socket, on the other hand, have been found to have an adverse impact on immediately implanted implants [2].

Animal and human studies have shown that immediate implants placed into infected postextraction sockets are a predictable procedure with success rates close to 92.37%. Even in cases requiring bone tissue enhancement and preservation, immediate implant placement has been described as a successful technique [3] [4].

To enhance bone growth and periodontal regeneration, bone replacement grafts are routinely applied. To organize bone replacement grafts, multiple classification systems have been employed, which generally include source (e.g., allograft), chemical composition (e.g., calcium phosphate), and physical qualities (e.g., ceramic) [5].

Calcium phosphate bone replacements, which are chemically equivalent to human bone, have been widely used among many bone graft materials used in socket preservation. Osteon II is an alloplastic substance made up of 70% hydroxyapatite and 30% beta tricalcium phosphate, which is the most similar mineral component to human bone. It's an osteoconductive substance that functions as a scaffold for bone formation and it possesses a porosity structure that is comparable to that of human cancellous bone, with linked porosity [6] [7].

Several studies have found that adding Hyaluronic acid (HyA) to an alloplastic bone graft for bone augmentation of alveolar defects can speed the initiation of new bone growth. HyA promotes osteoblastic bone formation by increasing mesenchymal cell differentiation and migration [8] [9].

Hyaluronic acid (HyA) is a naturally occurring biodegradable polymer of the extracellular matrix that is widely distributed throughout connective, epithelial, and neural tissues. HyA is a nonsulfated glycosaminoglycan composed of repeating glucuronic acid and N-acetyl-D-glucosamine. Its negative charge and high hydration ratio play an important role in the control of tissue hydration [10].

HyA plays a pivotal role in wound healing. The creation of a hydrated and non-adhesive environment enhances cell migration, whereas the interactions of proteoglycans with pericellular HyA impede migratory movements [11].

This clinical trial was conducted to compare the effectiveness of Osteon II collagen with hyaluronic acid versus Osteon II collagen alone for immediate implant

placement in infected sockets.

2. Patients and Methods

2.1. Study Design

This study was designed as a prospective randomized controlled trial (RCT).

2.2. Study Setting and Population

This RCT involved 20 Egyptian patients between the ages of 25 and 45, with 12 men and 8 women participating. Prior to beginning any of the study's steps, the Ethics Committee of the Faculty of Dental Medicine (Assiut branch), Al-Azhar University, Egypt, approved the protocol for the inquiry (AUAREC202300010-4). Patients enrolled in this study were selected from Outpatient Clinic at Department of Oral and Maxillofacial Surgery's outpatient clinic at Al-Azhar University's Assiut Branch's Faculty of Dental Medicine.

Inclusion criteria:

- 1) Systemically healthy people (according to the Cornell Medical Index) between the ages of 25 and 45 are advised to have their mandibular molars extracted if endodontic therapy failed or the teeth were severely damaged were included [12].
- 2) This RCT included females who did not use oral contraceptives [13].
- 3) This RCT included patients who had infected teeth, enough bone, and enough inter-occlusal space [13] [14].
- 4) Patients with mandibular molar teeth exhibiting chronic infection-related periapical lesions and periapical radiolucency, as diagnosed using preoperative CBCT, were included [15].
- 5) Patients with a crestal ridge width of 5 mm and a corono-apical height of at least 8 mm, both of which are significant anatomical features according to CBCT images obtained prior to surgery were included [14].

Exclusion criteria

We excluded the following:

- 1) Patients with a mandibular molar tooth with acute infection or prominent signs of periodontal or periapical infections [14] [15].
- 2) Mandibular molar tooth that had an apical fenestration or extraction socket with buccal or lingual wall defects [15].
- 3) Patients with parafunctional habits like clenching and bruxism, insufficient inter-occlusal space, and insufficient bone volume [13]-[15].
- 4) Patients with illnesses or medications that could impair healing or osseointegration like uncontrolled diabetes mellitus and osteoporosis [13]-[15].
- 5) Patients with poor oral hygiene and habits like heavy smoking and alcoholism could reduce blood flow and slow healing [13]-[15].

2.3. Sample Size Calculation

Based on the previous study of Baiomy (2019) [14], a power calculation of sample

size indicated that a minimum of 10 subjects per group were required to detect a significant difference between groups. The effect size ($df = 9.726$) and the required sample size were calculated for a 95% confidence interval and a power of (0.4606).

2.4. Randomization

A restricted randomization strategy was utilized to ensure the equitable allocation of patients to the therapy group. Patients were randomly assigned using computer randomization (<http://www.randomlists.com>) into two groups of ten patients each (6 males and 4 females).

2.5. Subject Grouping

Twenty participants (12 men and 8 women) were divided into two groups at random. Each group had an instantaneous implant along with their matched group according to the type of grafting material as follows: Group I: A control group of 10 patients who received immediate dental implants with Osteon II collagen graft only (6 males and 4 females). Group II: A study group of 10 patients who received immediate dental implants with Osteon II collagen with Hyaluronic acid graft (6 males and 4 females).

2.6. Surgical Procedure

Before surgery, all patients' mouths were rinsed with 20 ml chlorhexidine gluconate 0.12% solution or 30 seconds as a topical antimicrobial agent. A surgical site was locally anaesthetized by Artinibsa 40 mg/0.01mg/ml (Articaine hydrochloride + Epinephrine (adrenaline)). Atraumatic tooth extraction was done by using elevators to avoid any trauma during extraction and forceps of anatomic design that rotate the root in a clockwise-counterclockwise fashion to retrieve the root from the alveolus. After extraction, the socket was degranulated with curettes to remove all remnants of the periodontal ligament and granulation tissue. The drilling of implant was done in sequential manner. The implant was removed out of its vial and inserted about 2 mm apically to the extracted tooth according to determined length and width and to the analysis of each case that was done by cone beam computed tomography. Ratchet was used to insert the implant and tight in its site in a clockwise direction. Smart peg was applied to implant fixture for determination and reading the primary stability with implant stability quotient (ISQ) ostell. The cover screw was removed from the bottom of the implant vial by a hex tool and screwed into the implant body. In Group I, Osteon II collagen graft only was applied around dental implant as a graft material (**Figure 1**). In Group II, Osteon II collagen with Hyaluronic acid graft was applied around dental implant as a graft material (**Figure 2**). A biodegradable collagen membrane barrier that used to cover the graft. A resorbable suture used to close the socket.

2.7. Follow-Up Evaluation Protocols

The radiographic follow-up protocols were carried out in this current RCT at the

baseline (postoperative), 3 months, and 6 months observation periods. The clinical follow-up protocols were carried out in this current RCT at 6 months, and 9 months.

2.8. Clinical Evaluation

2.8.1. Post-Operative Infections

Early follow-up was done a week after the graft was placed to check for any post-operative infections [13].

2.8.2. Peri-Implant Probing Depth (PPD)

Using a Williams probe, the PPD was evaluated at four places around implants [14]. The distance between the gingival margin and the greatest apical PPD was determined by inserting a Williams probe into the peri-implant sulcus [15].

2.8.3. Implant Stability Quotient (ISQ)

Changes in the ISQ were documented utilizing the Osstell™ system for primary stability. The mean baseline ISQ value for each implant was determined by averaging three ISQ measurements made immediately after implant insertion. At the 6-month follow-up visit for prosthetic surgeries, additional resonance frequency analysis (RFA) measurements were done [14]. A measurement of Osstell, ranges from 1 to 100, with 100 denoting the maximum implant stability [13].

2.9. Radiographic Evaluation

2.9.1. Marginal Bone Loss Measuring

After three and six months, CBCT was used to quantify the crestal bone loss at the mesial, distal, buccal, and lingual surfaces of each implant [15] [16]. Using the ruler measure feature of the software, the distance between the implant abutment junction and the bone contact with the implant was measured to determine the marginal bone level [15]. Marginal bone height was assessed at the mesial and distal surfaces of each implant in the panoramic window of the CBCT software.

The marginal bone height at the buccal and palatal surfaces of each implant was measured in the CBCT software's cross-sectional window [16]. Alveolar bone heights during subsequent visits were subtracted from the bone level at the baseline in order to assess crestal bone loss [15] [16]. All implants' mesial, distal, buccal, and lingual bone loss measurements were added up, and the average was employed in the analysis [15].

2.9.2. Measuring of Bone Density

Using CBCT software, the average density at the marginal and crestal bone around the implant is determined. Regions of Interest (ROI) were chosen and traced (colour density selection) using this software. To automatically pick all other pixels in the ROI, a single pixel representing a certain colour (in radiography, white) is chosen, or a threshold is applied [13] [14]. The threshold areas are traced and recorded as a number of pixels that may be calculated as a ratio of the entire ROI [13] [14]. On the day of implant placement (the baseline), as well as at the 3, and 6 months follow-up visits, bone density was measured [14].

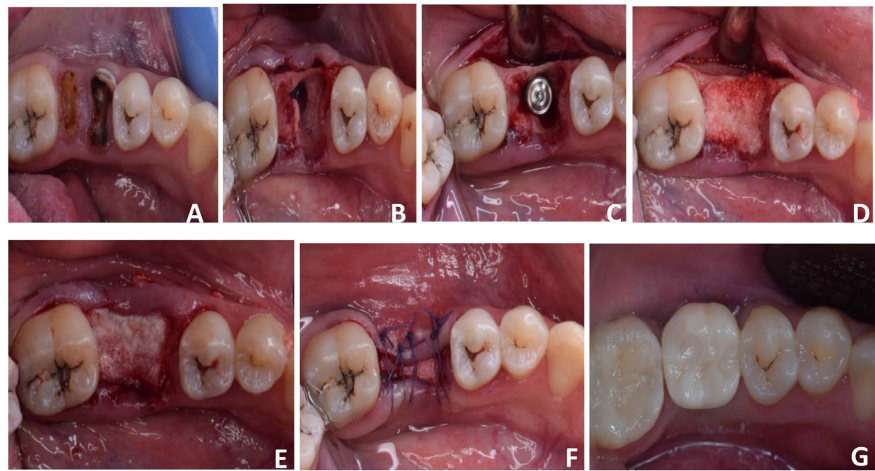


Figure 1. Clinical photographs of 22 years old female patient showing (A) Badly destructed tooth (B) Flap reflect and socket degranulation (C) Implant placement (D) Osteon II collagen without HyA application to fill peri-implant distraction gap (E) Biodegradable collagen membrane barrier that used to cover the artificial grafting bone material (F) Final suture (G) Final Restoration (Screw Retained zirconium crown). [Group I: control group.]

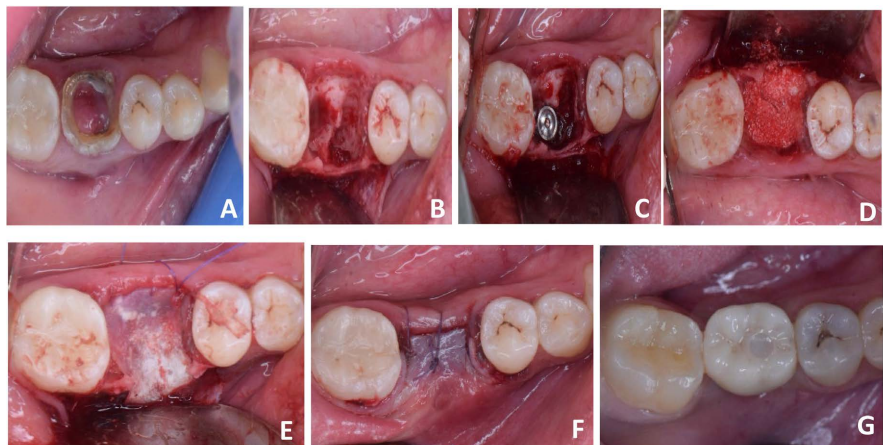


Figure 2. Clinical photographs of 22 years old female patient showing (A) Badly destructed tooth (B) Flap reflection and socket degranulation (C) Implant placement (D) Osteon II collagen with HyA application to fill peri-implant distraction gap (E) Biodegradable collagen membrane barrier that used to cover the artificial grafting bone material (F) Final suture (G) Final Restoration (Screw Retained zirconium crown). [Group II: study group.]

2.9.3. Statistical Analysis

Version 20.0 of the IBM SPSS software program (Armonk, NY: IBM Corp.) was used to analyze the data once they were loaded into the computer. Number and percentage were used to describe qualitative data. The normality assumption was checked based on the Shapiro-Wilk Test. The range (minimum and maximum), mean, standard deviation, and median were used to characterize quantitative data. For qualitative data, the Chi-square test was used. To compare two groups under study, the following tests were used: Independent t-test for typically quantitative two variables. Mann Whitney U was used to determine the significant test for non-parametric data between the two groups. For comparison of typically quantitative

data of more than two variables, one-way ANOVA test was used. At the 5% level, significance of the results was determined.

3. Results

Regarding PPD, there was no statistically significant difference between 6 months and 9 months in both groups. There was no statistically significant difference at 6 months and 9 months between Group I and Group II (**Table 1**).

Table 1. The mean $\pm$ standard deviation (SD) values of Peri-implant Probing depth (PPD) in mm of both groups.

Variables	Peri-implant Probing depth (PPD)								p-value
	Group I				Group II				
	Mean	SD	Min	Max	Mean	SD	Min	Max	
After 6 m	1.61 ^{aA}	0.55	1.00	2.50	1.44 ^{aA}	0.17	1.25	1.75	0.394 ns
After 9 m	1.75 ^{aA}	0.52	1.25	2.75	1.56 ^{aA}	0.17	1.25	1.75	0.297 ns
p-value	0.051 ns				0.104 ns				

Means with different small letters in the same column indicates significant difference, means with different capital letters in the same row indicates significant difference. *: significant ($p < 0.05$) ns; non-significant ($p > 0.05$).

Regarding the Modified Bleeding Index (mBI), there was no statistically significant difference between 6 months and 9 months in group I, while there was a statistically significant difference between 6 months and 9 months in group II. There was no statistically significant difference at 6 months and 9 months between Group I and Group II.

Regarding implant stability, there was a statistically significant difference between baseline and 6 months in both groups. There was no statistically significant difference at baseline and 6 months between Group I and Group II (**Table 2**).

Table 2. The means $\pm$ standard deviation (SD) and p-values of implant stability in ISQ of both groups.

Variables	Implant stability quotient (ISQ)								p-value
	Group I				Group II				
	Mean	SD	Min	Max	Mean	SD	Min	Max	
Baseline	72.89 ^{bA}	4.70	68.00	78.00	74.00 ^{bA}	8.47	61.00	84.00	0.735 ns
After 6 m	83.00 ^{aA}	5.20	77.00	89.00	87.67 ^{aA}	6.50	80.00	95.00	0.112 ns
p-value	<0.001*				<0.001*				

Means with different small letters in the same column indicate a significant difference, means with different capital letters in the same row indicate a significant difference. *: significant ($p < 0.05$) ns; non-significant ($p > 0.05$).

Regarding marginal bone loss (MBL), in Group I, there was a statistically significant difference between baseline, 3 months and 6 months. A statistically significant difference was found between baseline and each of 3 months and 6 months. Also, a statistically significant difference was found between 3 months and 6 months. In Group II, there was a statistically significant difference between baseline, 3 months and 6 months. A statistically significant difference was found between baseline and each of 3 months and 6 months. There was no statistically significant difference at baseline and 3 months between Group I and Group II. There was a statistically significant difference at 6 months between Group I and Group II (**Table 3**).

Table 3. The mean $\pm$ standard deviation (SD) and p-values of marginal bone loss in mm of both groups.

Variables	Marginal bone loss								p-value
	Group I				Group II				
	Mean	SD	Min	Max	Mean	SD	Min	Max	
Baseline	0.00 ^{cA}	0.00	0.00	0.00	0.00 ^{cA}	0.00	0.00	0.00	1 ns
After 3 m	0.17 ^{bA}	0.13	0.00	0.30	0.13 ^{bA}	0.10	0.00	0.20	0.556 ns
After 6 m	0.40 ^{aA}	0.09	0.30	0.50	0.30 ^{aB}	0.09	0.20	0.40	0.026*
p-value	<0.001*				<0.001*				

Means with different small letters in the same column indicates a significant difference, means with different capital letters in the same row indicates a significant difference; *: significant ($p < 0.05$) ns; non-significant ($p > 0.05$).

For PPD, the PPD showed positive correlation with all parameters, the strongest correlation was found with MBI while weakest correlation was found with bone density. For MBI, the MBI showed positive correlation with all parameters except with bone density, the strongest correlation was found with MBL while weakest correlation was found with bone density. For implant stability, the implant stability showed positive correlation with all parameters, the strongest correlation was found with MBI while the weakest correlation was found with bone density. For bone density, the bone density showed positive correlation with all parameters except with MBI, the strongest correlation was found with MBL while weakest correlation was found with implant stability. For MBL, the MBL showed positive correlation with all parameters, the strongest correlation was found with bone density while weakest correlation was found with implant stability (**Table 4**).

4. Discussion

In this study, during the baseline, the PPD assessment results revealed no statistically significant difference between the both groups at the baseline (6 months) and after 3 months (9 months). Moreover, the results of the current RCT revealed that

during the baseline and after 3 months, the ISQ test on the same side did not reveal any statistically significant differences. These clinical results could be explained fact that both groups used the same approach to protect the soft tissue and blood supply at the implantation site and to use tension-free interrupted sutures can be attributed to these outcomes [14] [15]. Furthermore, these clinical results could also be explained by the fact that both groups covered the surgical site beneath soft tissue flaps with collagen membranes, which prevented epithelium from migrating to the apex and facilitated connective tissue regeneration [17].

Table 4. Correlations between the different parameters in both groups.

		Peri-implant Probing depth (PPD)	Modified Bleeding index (MBI)	Implant stability quotient (ISQ)	Bone density	Marginal bone loss (MBL)
Peri-implant Probing depth (PPD)	Spearman Correlation	1.000	0.303	0.099	0.022	0.220
	p-value		0.072	0.564	0.900	0.198
Modified Bleeding index (MBI)	Spearman Correlation	0.303	1.000	0.225	−0.088	0.380*
	p-value	0.072		0.187	0.610	0.022
Implant stability quotient (ISQ)	Spearman Correlation	0.099	0.225	1.000	0.014	0.201
	p-value	0.564	0.187		0.935	0.239
Bone density	Spearman Correlation	0.022	−0.088	0.014	1.000	0.447**
	p-value	0.900	0.610	0.935		0.001
Marginal bone loss (MBL)	Spearman Correlation	0.220	0.380*	0.201	0.447**	1.000
	p-value	0.198	0.022	0.239	0.001	

Moreover, the insignificant clinical finding in this RCT between the both tested groups could be related to the fact that the drilling was done while being irrigated with copious normal saline for optimal cooling and to prevent overheating the bone tissue, which would affect osseointegration. The implant bed was prepared using a low speed, high torque handpiece [13] [18].

In terms of PPD, the study group (Osteon II Collagen with Hyaluronic Acid) had lower PPD values than the control group (Osteon II Collagen alone), but there were statistically significant differences between the two groups after six-month following surgery. Moreover, the study group showed improvement in the stability as mean were (87.67) and (83.00), respectively. But there is no statistical significance was observed between both groups and this minimal, may be attributed to the effect of HyA in the osteoblast and stem cells differentiation. But there is an improvement in stability.

These results matched with the result of Baiomy A.'s study in 2019 [14]. Previous finding which stated that when hyaluronic acid coupled with Osteon II colla-

gen it successfully promotes clinical success in extraction socket repair. Moreover, these clinical results were supported by the results of histological analyses by Taman *et al.* (2017) [13] which revealed that the use of hyaluronic acid provides a better and quicker healing process.

These results agreed with the results of previous study by De Arajo Nobre *et al.* (2007) [19] who stated that a healthy peri-implant complex can be maintained in immediate function implants for full rehabilitations in the edentulous mandible, according to the researchers' findings from their study. Additionally, Wanden Boogaerde's work (2009) [20] which examined 19 deep periodontal abnormalities supports this, where using esterified hyaluronic acid, the average PPD was reduced to 5.8 mm, gingival recession increased to 2.0 mm, and attachment increased to 3.8 mm one year after the therapy.

However, these results in agreement with the results of Baiomy (2019) [14] who stated that no statistically significant difference with regard to PPD and ISQ between the Osteon II collagen coupled with hyaluronic acid group and the Osteon II collagen only group.

In this study regarding to clinical implant mobility, no implant movement was observed in any implant over the course of the follow-up period in both groups, according to Roos *et al.* (1997) [21], this is one of the key indicators of an implant's success.

Moreover, the time-dependent crestal bone loss in this RCT was expected and could be explained by the bone's response to implant loading and healing [22]. Another study made a similar observation, reporting that from one to three years after implant placement, crestal bone loss rose dramatically for both infected and healthy sockets [23].

Additionally, as compared to the control group (Osteon II collagen only), the study group (Osteon II collagen coupled with hyaluronic acid) had statistically significant differences at all intervals, according to the radiographic results of the current trials measurements of bone density [14].

When HyA was added to the autogenous bone in the extraction sockets, Taman *et al.* (2017) [13] in previous histomorphometric studies discovered that the mean area percent filled by bone trabeculae was significantly higher compared to the control group when just the autogenous bone graft only were employed.

From a histological point of view and its coordination with the radiographic findings in this study in the form of bone density, which lead to reduction in the time of bone maturation due to the effect of HyA on bone graft (Osteon II collagen) remodeling.

Moreover, the radiographic finding of the present RCT revealed that when the study group (Osteon II collagen coupled with hyaluronic acid) was compared to the control group (Osteon II collagen only), marginal bone level data revealed a significant statistically difference over a 6-month period with the better and significant results was found in the study group and these results was agreement with Taman *et al.* (2017) [13].

Kim *et al.* (2016) [24] who used HyA to freshly extracted sockets with prior infected socket concurred with these findings. They discovered that HyA may promote bone growth and quicken wound healing in infected sockets due to its osteoinductive, bacteriostatic, and anti-inflammatory effects. Additionally, Aslan *et al.* (2006) [25] findings demonstrated that Osteon II collagen with hyaluronic acid groups have a superiority in bone healing histologically were corroborated by these findings.

These results of this study in agreement with results of Baiomy (2019) [14] who used osteon II collagen with HyA which has superior effect and promotes bone growth more quickly than osteon II collagen alone. But our results disagree with Eric Aguado *et al.* (2014) [8] looked at the use of hyaluronic acid as an aqueous binder of the TCP bone graft granules, as they discovered that, in contrast to our findings, the amount of gained bone was not noticeably larger than with TCP granules alone.

According to Albrektsson *et al.* (1986) [26] the implant success criteria, which include no radiographic peri-implant radiolucency, no infection, and bone loss of less than 2 mm, were applied. If the implant is still working and meets the success criteria, it is regarded as having survived. Therefore, the all immediately placed implants in his current RCT were successful according to this preview criteria of Albrektsson *et al.* (1986) [26] because they did not record any radiographic radiolucency or bone loss.

Finally, in terms of pocket depth and ISQ at a 6-month interval, osteon II collagen with HyA performs better clinically than osteon II alone. In terms of the radiographic examination, the second group also performs better on the following measures: crestal bone height and bone density at intervals of 3 and 6 months.

5. Conclusions

The following conclusions can be addressed within the constraints of this study:

The usage of Osteon II Collagen with Hyaluronic acid appears to be effective in jumping zone grafting around immediate implant in the infected extraction sockets. Adding hyaluronic acid to Osteon II Collagen minimizes post-operative complications and improves the success rate of immediate implant. Osteon II Collagen with hyaluronic acid showed a non-significant change in PPD compared to the control group at 6 months. Adding hyaluronic acid to Osteon II Collagen contributes to increased bone density, enhanced implant stability, reduced MBL, and shorter healing time.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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