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Clinical And Radiographic Assessment of Xenogenic Bone Graft with or Without Hyaluronic Acid For Post Extraction Socket Preservation (Randomized Clinical Trial)

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ABSTRACT

Aim: hyaluronic acid shows osteogenic potentials which considered important property during bone regeneration. So, we aim to assess the efficiency of hyaluronic acid with xenograft mixture in post extraction alveolar sockets to decelerate resorption of dental alveolar ridge. **Materials and Methods**: A total of twelve patients with twenty nonrestorable maxillary premolars, which were extracted atraumatically are included in this study. Twenty extracted sockets were divided randomly into two equal groups. Sockets were grafted as follows: Group (I) sockets were grafted by xenograft mixed with hyaluronic acid; Group (II) sockets were grafted by xenograft alone. CBCT scans are made for each patient to measure bone density while pain assessment was done by VAS (visual analogue scale) for pain postoperatively. **Results:** All preserved sockets enrolled in this study received final crowns over the abutments and the Osseo integrated implants were in fully function position without any complication. According to VAS pain recorded a higher mean value (7.4±1.35) for Group (I), in comparison to Group (II) (4.2±1.48). The differences between study and control groups were statistically significant (p=0.00). While Radiographic bone density Group (I) recorded a higher mean value (879.09±118.76), in comparison to Group (II) (546.18±123.61). The differences between study and control groups were statistically significant (p=0.00) **Conclusion:** The results clearly concluded that both groups are successful in achieving clinical and radiographic socket preservation with superiority for xenograft mixed with hyaluronic acid.

1. INTRODUCTION

Maintaining healthy teeth is one of the objectives of periodontal therapy so that patients can benefit from health, function, and aesthetics. But occasionally, tooth extraction is unavoidable due to conditions like caries, periodontal disease, endodontic lesions, and others. [1].

Tooth extraction establishes unfortunately a sequence of biological changes, with dramatic alveolar ridge resorption , mucosal invasion to underlaying tissue, just in the first weeks following extraction [2,3]. Alveolar ridge resorption occurs in all circumstances as a result of changes to the amount and extent of the bone remodelling , which are depending on a number of variables. [4,5].

There are several treatment modalities offered to the patients as an replacement to substitute their missing teeth, from removal dentures to fixed dental prosthesis, from dental implants to adhesive fixed prosthesis, each of them with excellent outcomes with high survival rates for follow-ups terms which was reported in the literature, when well indicated [6,7].however, All these options don´t solve the physiological changes and volumetric decrease that occur after tooth extraction.

In the last years, Any dental procedure's primary goal was not only to treat the underlying issue, but also to avoid it altogether or at the very least lessen the rate of resorption of both hard and soft tissues over time. Clinicians have a variety of options for achieving this goal thanks to a variety of technologies and methodologies. The clinician now has a variety of options with a variety of indications and a variety of levels of scientific background, ranging from socket shield technique to immediate implants or even alveolar ridge preservation [8] .

There are many different alveolar ridge preservation treatment modalities that have been described previously, besides the socket grafting with a biomaterial alone[9], buccal shielding for restoring buccal bone contour [10], covering the socket by biological membrane either autogenous or synthetic, or a combination of some of them, with or enhances primary intention healing using soft tissue graft. [11].

Even using osteogenic material like Hyaluronic acid (HA) Its biocompatibility, biodegradability, and nonimmunogenicity are all biological processes in relation to tissue healing and morphogenesis.[12]. Its physicochemical characteristics also allow it to mediate osteoclast adhesion to the surface of the bone and retain osteoinductive growth factors in the local environment. [13]. In order to prevent the resorption of the alveolar ridge, we therefore aim to evaluate the effectiveness of HA with xenograft mixture in post-extraction alveolar sockets.

2. PATIENTS & METHODS

The research was carried out in 20 dental sockets of 12 patients chosen from the outpatient clinic of the department of oral and maxillofacial surgery at Future University in Egypt. All patients read and signed the informed consent participation of the study and development for the guidelines outlined in the Declaration of Helsinki for human experimentation. The study was approved by the research ethics committee board- Future university in Egypt.

Patients were selected according to specific criteria.

A- Inclusion criteria:

Unrestorable maxillary premolar indicated for extraction of patients between the age group of 19 and 48 years.

B- Exclusion criteria[14]:

Patients with Uncontrolled systemic disease e.g., “diabetes mellites, hypertension.... etc.”, Patients with severe parafunctional habits such as bruxism and clenching. Patients have poor maintenance of oral hygiene. Pregnancy. Heavy smokers (more than 20 cigarette/day).

Patients taking any medications that could compromise healing “Immunosuppression drugs, bisphosphonates”. Unrestorable tooth which is not alignment with the proposed implant osteotomy. Root with dehiscence of more than 50% of the total socket surface on either buccal or lingual wall at time of extraction. Patient needed surgical extraction.

Randomization

Extracted sockets classified randomly into the following two equal groups using online software (http://ranomizer.org)

Grouping:

20 extracted sockets were divided randomly into two groups.

Group (I): 10 extracted sockets were filled with mixture of xenograft and hyaluronic acid gel and covered with PRF.

Group (II): 10 Extracted sockets were filled with xenograft and covered with PRF membrane.

Ethical consideration

The ethical clearance was obtained by the research ethical committee of Future University in Egypt before the study got underway once the chosen patients were made aware of its purpose and given their informed permission.

Materials used(fig.1):

- Hyaluronic acid Hyalubrix® (Fidia Farmaceutici, Abano Terme [PD], Italy) is a 1.5% (15 mg/ml) HA solution with a molecular weight between 1.5 and 2.0 MDa that was prepared through biofermentation.
- Xenograft material used in this study was a bovine cancellous xenograft Tutobone® (Tutogen Medical GmbH, Neunkirchen a. Brand, Germany) The particle diameter of this biological organic bone replacements material ranges from 0.25 mm to 1 mm.

Figure (1) — Photographs of material used in the study (a) hyaluronic acid Hyalubrix®. (b) xenograft Tutobone®

- **Intervention:**

A. Presurgical phase:

To achieve the best patient selection in accordance with the inclusion criteria, each patient had a clinical investigation and they were also subjected to a thorough history taking, local, visual inspection, and examination of the complete oral and perioral tissue and preoperative periapical image to ensure absence of preapical lesion (fig.2).

In order to assess the interarch relationship and the interocclusal space that could accommodate the implant abutment and the future crown restoration both clinically and on the study models, primary alginate impressions for both arches must be taken. These impressions will be used to cast diagnostic study models.

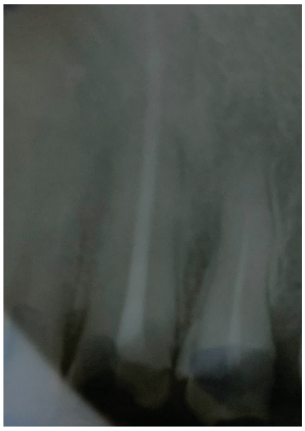

Figure (2) — Preoperative Preapical radiographic image

B. PRF membrane Preparations

In advance of extraction, each of the two sterile, 10-ml noncoagulated vacuum tubes was filled with approximately 20 ml of the patients' whole venous blood. The vacutainer tubes were spun at 2700 revolutions per minute (rpm) for 12 minutes in a centrifugal machine. The fibrin clot was removed from the red blood cell layer and slightly compressed to create the PRF membrane after centrifugation was complete. (fig. 3).

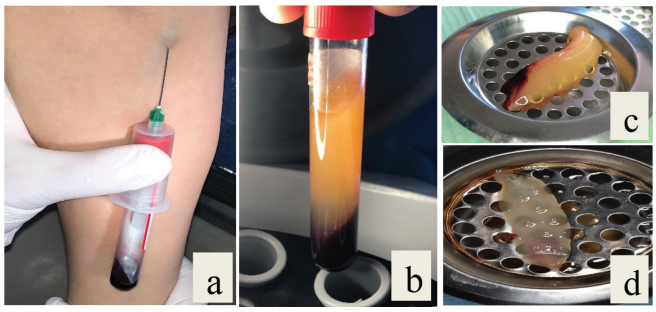

Figure (3) — Photographs of steps PRF membrane preparation (a) collection of venous blood, (b) Formed PRF clot, (c) Separated PRF clot from RBCs layer, (d) Compressed PRF membrane.

C. Extraction phase

Tooth extraction was performed with atraumatic procedure under local anesthesia (Articaine hydrochloride 4% with 1:100,000 epinephrine, Artinibsa, Inibsa, Spain) using fine flexible periotome without elevating a flap and socket department through exploring extracted socket for any pathological lesions using small curette and irrigation with the normal saline in both groups (fig. 4).

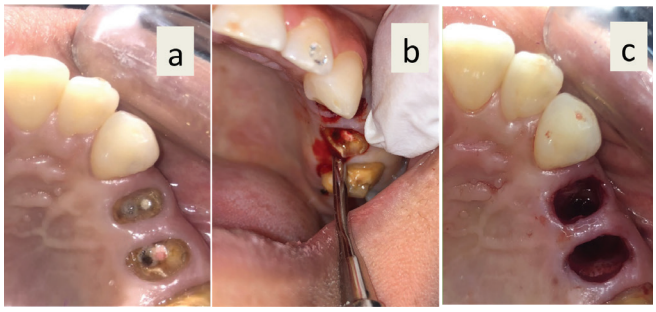

Figure (4) — Photographs of extractions steps. (a) Preoperative clinical photography, (b) Atraumatic extraction by periotome, (c) Clean extracted sockets

D. Grafting phase(fig.5):

Each socket was grafted and classified into: -

- **Group (I)** socket was filled with mixture of (0.5cc) xenograft and hyaluronic acid gel with ratio 1:1.
- **Group (II)**socket was filled with (0.5 cc) xenograft material wetted with saline.

In both control and study group the socket covered with PRF membrane and sutures were performed on PRF membrane (figure of eight, resorbable suture material polyglycolic acid (Assucryl, Switzerland) (fig. 6).

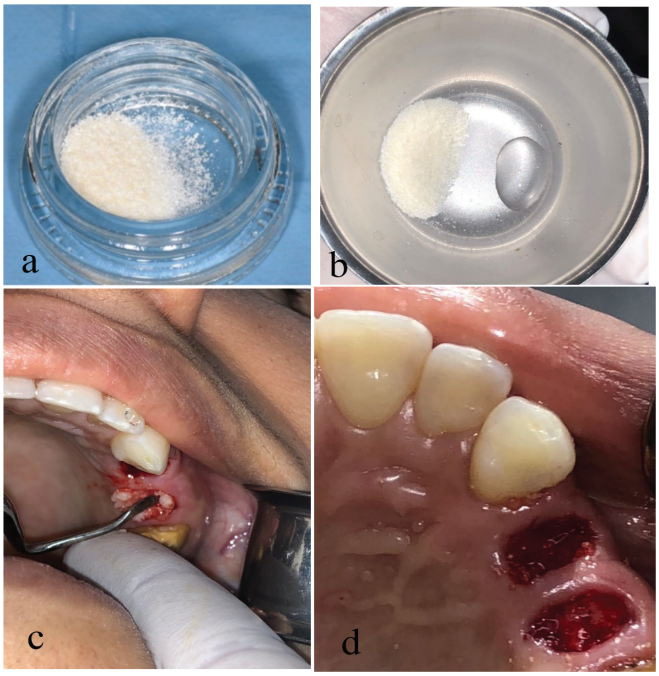

Figure (5) — Photographs of grafting phase (a)In Group (II) group xenograft wetted with saline, (b)In Group (I) mixture of hyaluronic acid with xenograft, (c)Application of grafting material into extracted socket, (d)Grafted socket

All patients received Postoperative medications including:

a. A dose of one capsule every 12 hours for five days is recommended antibiotic of amoxicillin 875 mg/clavulanic acid 125mg (Augmentin 1gm tablets, GlaxoSmithKline (gsk), Cairo, Egypt).

b. Ibuprofen 600 mg, a non-steroidal anti-inflammatory medicine, at a dosage of one tablet every 12 hours for three days (Brufen Tablets 600mg, Abbott, Cairo, Egypt).

c. Use warm chlorhexidine gluconate solution as a mouthwash for a week to help with plaque control (Hexitol mouthwash, Arab pharma company, Cairo, Egypt).

Patient was recalled after 7 days to remove the sutures.

e. Post extraction phase

1 week after extraction

Any signs of infection or inflammation is recorded as well as VAS for pain is assessed .

3 months after extraction another CBCT scan was preformed to determine the dimension changes in socket, bone density and measure of alveolar bone length and width of preserved socket for implant planning and placement by blue sky bio implant planning software version 3 (Blue Sky Bio, Libertyville, IL) (fig. 7)

h. Surgical phase for implant placement after 3 months of healing

Full-thickness envelope flap was elevated over the preserved socket while receiving local anaesthetic (Articaine hydrochloride 4% with 1:100,000 epinephrine, Artinibsa, Inibsa, Spain).

Implants were inserted and then finally seated down to full depth, then flap was sutured (fig.8).

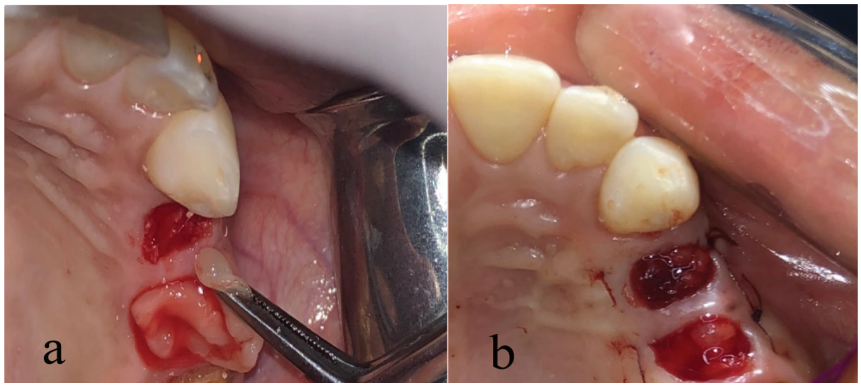

Figure (6) — Covering of grafted socket with PRF membrane (a), Suturing the PRF membrane (b)

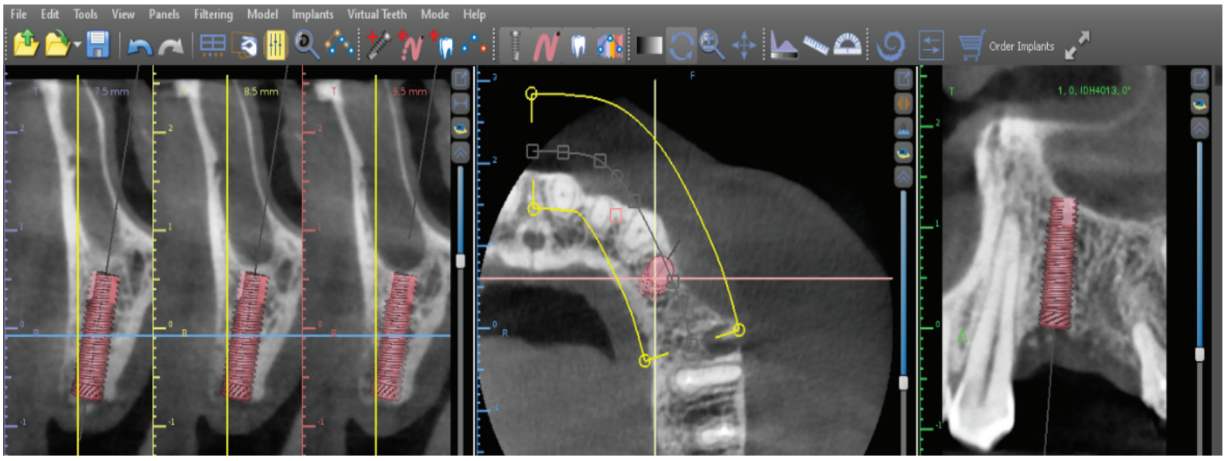

Figure (7) — Planning for implant placement

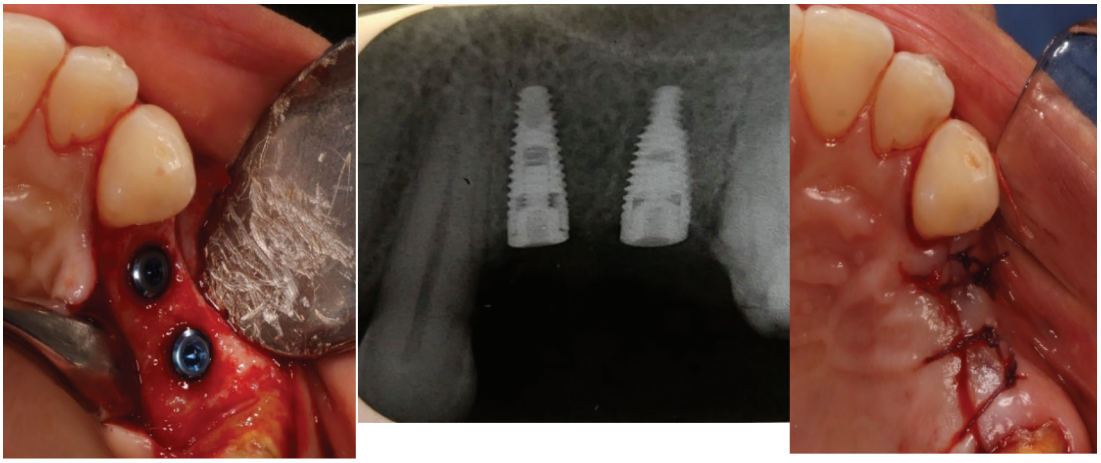

Figure (8) — Photographs of implant placement and suturing

i. Post-implant placement follow-up

Following the insertion of the implants, the sutures were removed, and each patient underwent a clinical evaluation for the presence of pain or infection after one week.

j. Prosthetic phase

Final prosthesis was delivered over the abutments three months after implant insertion, and functional loading on the fully Osseo integrated implants (fig .9).

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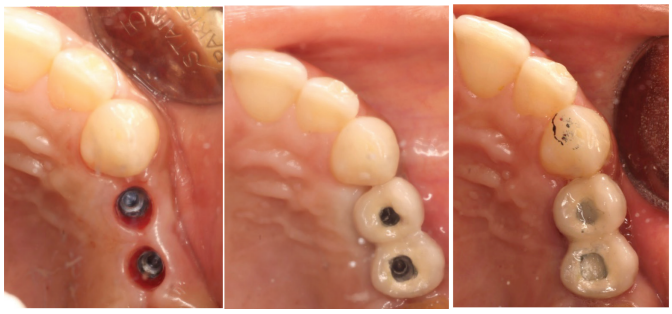

Figure (9) — Final functional prothesis was delivered

k. Post operative Assessments

I. Clinical evaluation

In one week after extractions follow up:

VAS pain: visual analogue scale for pain : The patient was instructed to write down on a 10 cm line how much pain they noticed during the first week following surgery. [15].

II. Radiographic bone density

Each and every patient in the study finished 3 months after grafting CBCT imaging by blue sky bio implant planning software version 3 (Blue Sky Bio, Libertyville, IL).

Statistical Analysis:

The Statistical Package for Social Sciences (SPSS) version 18 was used for management, and statistical analysis of the collected data. Utilizing the mean, standard deviation, and confidence interval, numerical data were summarised. Examination of data normality by checking the data distribution and preforming Kolmogorov-Smirnov and Shapiro-Wilk tests. Using an independent t test, groups were compared with regard to normally distributed numerical variables. The Paired t test was used to compare the results of the two observation times.

All p-values are two-sided. P-values ≤0.05 were considered significant.

3. RESULTS

All implants included in this study had shown sufficient secondary implants stability after six weeks of implant placement with no post-operative complications was noticed at any case.

I. Demographic data

Gender: In the study group, there were 20% men and 80% women, while in the control group, there were 40% men and 60% women.

There was no statistically significant difference between the groups(p=0.329), (Table 1, Fig. 10)

Age: In the study group minimum age 19 years old and maximum age 48 years old with mean age 33.1±4.01 while in the control group contain 6 patient with minimum age 28 years old and maximum age 41 years old with mean age was 34.1±9.05 There is no statistically difference between both groups (p=0.75), (Table 1, Fig.11)

Table (1):

Comparison of demographic data between study and control groups.

			GROUP (I)	GROUP (II)	P value	Test used
Gender	Male	Count	2	4	0.329 ns	chi square test
		%	20%	40%		
	Female	Count	8	6		
		%	80%	60%		
Age (years)		Mean	33.10	34.10	.75 ns	Independent t test
		Std Dev	4.01	9.05		

Significance level p≤0.05, ns=non-significant

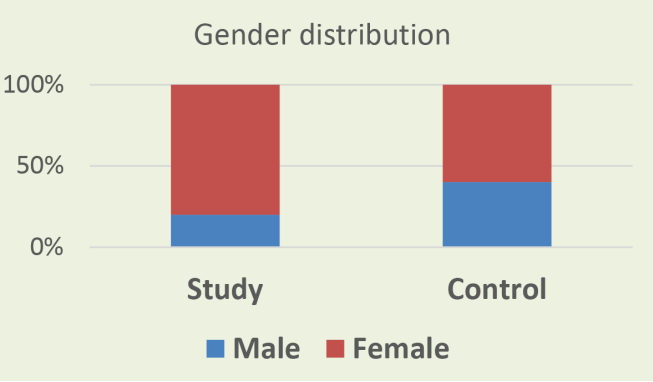

Figure (10) — Bar chart illustrating gender distribution of the study and control groups

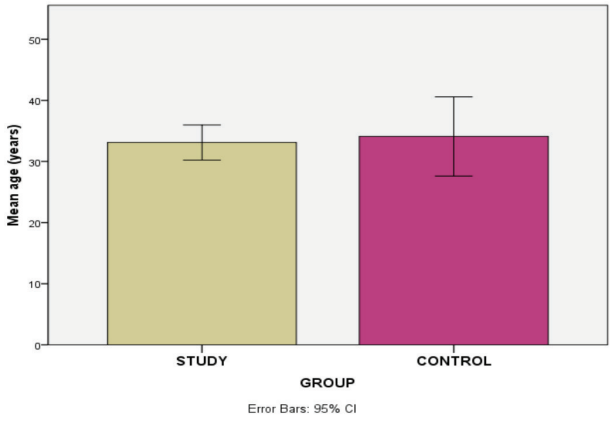

Figure (11) — Bar chart illustrating mean age (years) of the study and control groups

II. Clinical evaluation

After tooth extraction and ridge preservation, both groups finally experienced excellent soft and hard tissue healing , and no problems were noted for the whole research period.

Pain scale: Study group recorded a higher mean value (7.4±1.35), in comparison to control (4.2±1.48). The difference between groups was statistically significant (p=0.00), (Table 2, Fig. 12)

Table (2)

Descriptive statistics of Pain and swelling scale in comparison between control and study groups (independent t test)

	GROUP	Mean	Std. Dev	Difference				t	P
				Mean	Std error	C.I. upper	C.I. lower		
Pain scale	(I)	7.40	1.35	**3.20**	**.63**	**1.87**	**4.53**	5.06	0.00*
	(II)	4.20	1.48						

Significance level p≤0.05, *significant, ns=non-significant

C.I.= 95% confidence interval

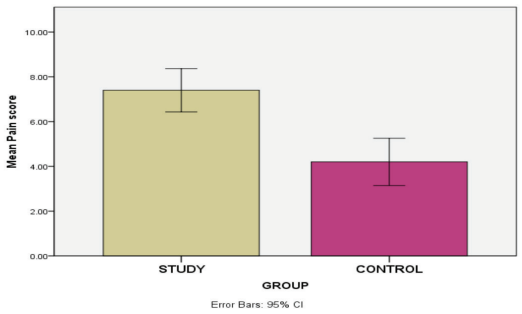

Figure (12) — Bar chart illustrating mean pain score in the study and control groups

Radiographic bone density (HU) Study group recorded a higher mean value (879.09±118.76), in comparison to control group (546.18±123.61). The difference between groups was statistically significant (p=0.00), (Table 3, Fig. 13)

Table (3)

Descriptive statistics of radiographic bone density (HU) and comparison between control and study (independent t test)

GROUP		Mean	Std. Dev	Difference				t	P
				Mean	Std error	C.I. upper	C.I. lower		
Bone density (HU)	Study	879.09	118.76	332.91	54.21	219.02	446.81	6.14	0.00*
	Control	546.18	123.61						

Significance level p≤0.05, *significant, C.I.= 95% confidence interval

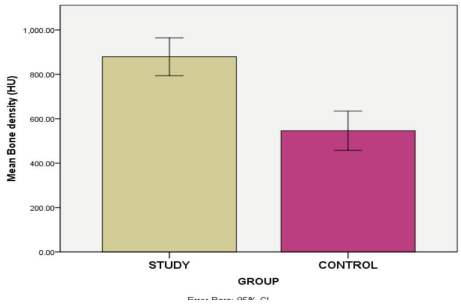

Figure (13) — Bar chart illustrating mean bone density (HU) of the study and control groups.

4. DISCUSSION

Following tooth removal, there is a progressive and irreversible process known as post extraction resorption of the alveolar ridge. When teeth are extracted, a serious chain of biochemical and histological events begins to play out that inevitably results in reduction alveolar bone and soft tissue. [16].

These alterations at the extraction site may be brought on by the loss of bundle bone, periodontal ligament fibres, and blood supply.Because the anatomical profile of the socket is defined by soft tissue recession and buccal plate resorption, which may limit the range of treatment options, these morphologic changes present significant challenges for restorative treatment[2].

Accordingly, augmentation of resorbed alveolar ridges and alveolar ridge preservation have been a goals and challenges of clinicians to create an excellent bone quality and size suitable for implant placement to optimize the outcomes [17].Regarding socket preservation, different grafting material have been used including: autogenous bone graft, allograft, xenograft and alloplasts [18].

In present randomized, controlled, clinical study, socket preservation was conducted in 20 sockets for 12 patients in which each socket was preserved using mixture of xenograft with hyaluronic acid (study group) and xenograft only (control group). For both groups the socket was grafted and covered with PRF membrane.

Based on the outcomes of the clinical examination that was performed during the follow-up period. Overall, all groups experienced minimal incidences of problems, with no issues in the implant or final restoration. whereas, without any evidence of infection or dehiscence, all patients exhibited promising soft tissue healing. Results showed that neither group experienced any surgical problems, including suppuration. This may be because many reasons including simple extraction without any signs of preoperative pathological infections ,this result was in agreement with **Diana** et.al [19] as a split mouth study was performed in a study group with oral HA ointment into the sockets while other group ,the socket left untreated , as Regarding the decrease of socket length and postoperative problems, they found no statistically significant differences between the two groups, but their findings showed that HA accelerates and improves the healing ability.

Another explanation was regenerative proprieties of PRF such as induce endothelial cell proliferation and improved wound angiogenesis and ability of HA to expedite wound closure and enhance microcirculatory perfusion at the site of tissue healing in the wound area. This is in the same side with **Bansal** et al [20] and **Roy** et al [21]. This is due to HA's capability to stimulate inflammatory cytokines like IL-1 and TNF- α, enhances angiogenesis, and turn on keratinocytes and fibroblasts during the healing process. [22] .Our outcomes were in acceptance with many studies [13, 23] which found that HA improves and expedites the repair process.

Our results did not agree with those of **Shamma** et.al [24] and **Aebli** et.al [25] who stated that HA has no discernible impact on the speed of healing or the ability to repair.

Regarding postoperative infection, no evidence of post-operative infection or dehiscence was noticed in this study. This may be due to the application of sterile surgical procedure, the use of antibiotic during postoperative and infection prevention propriety of PRF and HA. Where, PRF has high content of leukocytes which may have a part in controlling inflammation and preventing infection. This is in accordance with **Dohan Ehrenfest** et al report [26]. Also, HA has bacteriostatic and anti- inflammatory actions. This is in the same side with **Pirnazar** et al [27] study conclusion that stated at clinical application of HA gels may lessen bacterial contamination at the surgical wound site, lowering the risk of infection after surgery and encouraging more predictable bone regeneration. Also, **Kim** et al [28] found

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out that HA, Due to its bacteriostatic, anti-inflammatory, and osteoinductive properties, may promote bone regeneration and speed up wound healing in infected sockets.

Regarding postoperative pain, Study group recorded a higher mean value in comparison to control group. This result is in agreement with **Awartani and Tatakis** [29]study on ten systemically healthy adults who had at least one anterior site with class I or II interdental papilla loss were treated with hyaluronic acid gel. The results of this study showed that two of the patients expressed dissatisfaction with the procedure in terms of pain or discomfort during the first postoperative week, and many patients (5/9) rated the post-operative discomfort as the worst part of the overall the surgery. Also, **Bertl** et al [30] who used hyaluronic acid gel to treat deficient papilla in the anterior maxilla next to an implant-supported crown for twenty patients ,and found that Two patients experienced severe pain and swelling of the lip after the second injection. Our findings were not corresponding with **Becker** et al [31] and **Alhabashneh** et al,[32] as they concluded that no patient reported pain after hyaluronic acid gel injection to treat deficient papillae. No patient reported taking analgesic tablets after the injections.

In the present study, CBCT quantitative analysis software, with its low radiation dose and high repeatability, was used to analyse the changes in bone mineral density.To minimise human error, all procedures were carried out by the same physician, and the patient's position was preserved when taking CBCT scans at periodic times. Results of radiographic bone density for the study group revealed statistically significant differences in Hounsfield Unit (HU) for 3 months follow up than control group. This result was confirmed by previous study by **Taman** et al [14] as they used mixture of autogenous bone graft with hyaluronic acid after follow up in 6 months.

Baiomy et al, [33] study about sticky bone vs TCB with hyaluronic acid concluded that radiographic bone density scores had higher values in TCB with hyaluronic acid group than sticky bone group with highly statistically significant difference at 3, 6 month intervals

Eduardo and **Alcântara** [34] Describe how HA in post-extractive sockets exhibits greater bone volume at 30 days compared to the control but a negligible difference at 90 days in a cone beam analysis.

5. CONCLUSIONS

By the end of this study, we concluded that hyaluronic acid has stimulatory effect on osteoblast activities that appears radiographically as study group has statistically increase in radiographic bone density than control group with unfortunately a drawback regarding pain as patients of study group experienced post operative pain statistically higher than control group

6. RECOMMENDATIONS

Due to limited number of cases in this study further research is necessary using larger sample size. Study was conducted on maxillary premolar and hence all conclusions are limited to this site.

Further research in necessary to evaluate effect of xenograft and hyaluronic acid mixer in large bone defect and in site with presence of infection to evaluate the antibacterial effect of hyaluronic acid.

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Nil.

Conflicts of interests:

There are no conflicts of interests

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