EVALUATION OF THE SOFT TISSUE PROFILE FOLLOWING SOCKET PRESERVATION WITH PLATELET RICH FIBRIN (PRF) VERSUS FREE GINGIVAL GRAFT: A RANDOMIZED CONTROLLED STUDY.

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ABSTRACT

Aim: The aim of our work was to compare to evaluate the effect of platelet rich fibrin (PRF) versus free gingival graft (FGG) in preservation of soft tissue volume of extraction socket/ alveolar ridge, in terms of the soft tissue profile for assessment of the soft tissue changes.

Methodology: 26 patients with non-restorable teeth were included in this study for atraumatic extraction and socket preservation. Patients were divided equally and randomly assigned into either the intervention (PRF membrane) or the control group (FGG); after tooth extraction, socket was covered by either PRF membrane or FGG. Casts were obtained from each patient at baseline as well as 6 months postoperative for optical cast scanning, in order to measure the changes in soft tissue profile.

Results: In the current study, Insignificant difference (p=0.528) was found between the intervention and the control groups in terms of mean Soft tissue Profile changes in millimeters.

Conclusion: PRF membrane can be used as an alternative to FGG in alveolar socket preservation, due to it's important role in soft tissue healing as well as bone preservation with it's known sustained release of growth factors, that enhances the healing process.

KEYWORDS: atraumatic tooth extraction, Socket preservation, alveolar ridge preservation platelet rich fibrin (PRF), free gingival graft (FGG), soft tissue profile, soft tissue healing, Casts, optical scan.

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Introduction

Following tooth extraction, alveolar bone and soft tissues are remodeled. These remodeling changes were reported to be around 40-60% reduction in height and width of the remaining alveolar ridge, as well as reduction in the width of keratinized mucosa and thickness of the soft tissue in general corresponding to the changes in the external alveolar bone profile **(Tan et al., 2012; Farmer & Darby, 2013; Suttapreyasri & Leepong, 2013; Jambhekar et al., 2015; MacBeth et al., 2017)**.

Most of the alveolar ridge resorption takes place during the first 6 months postextraction with the highest amount of bone resorption at 3 months **(Schropp et al., 2003; Tan et al., 2012; Ali & Selim, 2018; Annunziata et al., 2018; Juodzbalys et al., 2019; Majzoub et al., 2019; Nisar et al., 2020)**.

The resorption of the alveolar bone postextraction was found to be more prominent horizontally than vertically, as well as buccally than lingually/palatally limited mainly to the marginal third of the ridge. This resorption leads to a narrower and shorter ridge located in a more lingual position **(Van Der Weijden et al., 2009; Horowitz et al., 2012; Jung et al., 2013; Areewong et al., 2019; Stumbras et al., 2019);** this is because of the thin bundle bone lining the socket walls which is a tooth-dependent structure so it diminishes after the tooth removal leading to soft tissue collapse **(Thalmair et al., 2013; Vittorini Orgeas et al., 2013; Flügge et al., 2015; Jambhekar et al., 2015; Jung et al., 2018)**.

A systematic review by **Tan et al., 2012** concluded rapid alveolar ridge resorption in the first 3-6 months post extraction, followed by continuous gradual reduction throughout life leading to subsequent esthetic, functional & biological challenges during the replacement of missing teeth. This resorptive process might be further increased by the extraction procedure itself. It was reported that alveolar ridge resorption is unavoidable, even when extraction is carried out in the most atraumatic way, as reported by several studies that nearly 60% and 40% of the bone's width and height respectively are lost within the first 6-12 months after extraction. Yet, atraumatic extraction helps minimize it **(Ashman A., 2000; Kotsakis *et al.*, 2014; Nisar *et al.*, 2020).**

Noteworthy, the biology of the extraction socket affects the success of implant placement in an ideal 3D position maintaining biological, functional and esthetic requirements **(Ten Heggeler et al., 2011; Flügge et al., 2015; Jambhekar et al., 2015)**.

Therefore, socket preservation techniques were introduced; it's a surgical procedure that is carried out to maintain and preserve the postextraction alveolar ridge dimension in an attempt to minimize the need for further augmentation surgical procedures for implant- or fixed prosthetic rehabilitations **(Mardas et al., 2015; Ali & Selim, 2018; Annunziata et al.,**

2018; Bassir et al., 2018). In a consensus conference , it was stated that socket preservation is important to preserve bone and soft tissue volume in case of fixed or removable prosthesis as well in case of implant-supported prosthesis (**Juodzbalys et al., 2019).**

A systematic review by **Vignoletti et al., 2012**, concluded the positive effect of socket preservation techniques in limiting the vertical and horizontal dimensional changes of the ridge, regardless the surgical procedure and the type of biomaterial used.

Generally, it has been agreed upon the fact that although socket preservation did not completely prevent ridge resorption, yet it is effective in the reduction of the resorptive process of the ridge, in comparison to unassisted healing, as well as they may decrease the need for further augmentation procedures during the replacement phase. Additionally, more success & survival rates of implants were reported in preserved sockets, compared to plain extraction sockets **(Ten Heggeler et al., 2011; Horowitz et al., 2012; Vittorini Orgeas et al., 2013; Jambhekar et al., 2015; Mardas et al., 2015)**.

For optimal implant positioning in the ideal 3D position, one of three techniques can be employed, either grafting, covering with barrier membrane or both. Bone grafts include autogenous grafts, allografts, xenografts and alloplasts; membranes are either resorbable or irresorbable. The use of these grafts and membranes in conjunction or separately, might interfere with the normal healing process postextraction minimizing ridge contraction **(Horowitz et al., 2012; Vittorini Orgeas et al., 2013; Kassim et al., 2014; Jambhekar et al., 2015)**.

Barone et al., 2013 highlighted the positive effect of flapless alveolar ridge preservation procedures compared to flapped procedures in their comparative prospective randomized clinical survey, where more resorption was found in the width of the alveolar ridge after extraction with the flapped technique. An increase in width of keratinized gingiva was detected with the flapless approach; therefore it was concluded that the flapless procedure is more superior to the flapped technique, in terms of alveolar ridge preservation and enhancement of soft tissue.

Studies concluded the effectiveness of free gingival graft alone in reduction of soft tissue shrinkage, due to primary closure leading to increased mechanical stability thus full consolidation of the graft with the extraction site **(Thalmair *et al.*, 2013)**.

Platelet rich fibrin was first introduced by **Choukron et al., 2000** as a second generation APC and since then it has been considered as an important surgical adjunct in many surgical procedures such as sinus lifting, alveolar cleft treatment, dental implants and most importantly alveolar ridge/socket preservation (Canellas *et al.*, 2019). Platelet-rich fibrin (PRF) is a complete autologous preparation with a tetramolecular structure formed of fibrin matrix with embedded

platelets, leukocytes, cytokines (1β, IL-6, IL-4 and tumor necrosis factor α), circulating stem cells and growth factors such as transforming growth factor-b (TGF-b), vascular endothelial growth factor (VEGF), platelet-derived growth factors (PDGFs) and insulin- like growth factor, necessary for wound healing and tissue repair. Unlike PRP, it releases the highest amount of TGF-1 at day 14 and the highest amount of PDGF at day 7, ensuring a slower and more sustainable release of growth factors, thus longer duration of action and easier cytokines incorporation. Its characterized by simple preparation without the need for activators as anti-coagulants or any other additives, resulting in a strong fibrin matrix **(Del Fabbro et al., 2017; Blinstein & Bojarskas, 2018; Canellas et al., 2019)**.

Suttapreyasri & Leepong, 2013 proved the positive effect of PRF on soft tissue enhancement with a better ridge contour during the first month after preservation, with clinically significant results for successful esthetic implant placement. This was on line with **Tan et al., 2012** systematic review which reported a higher gain in keratinized mucosa in favour of the PRF group, compared to collagen plug and unassisted healing (control) groups. As well as **Fujioka-kobayashi & Bishara, 2017** systematic review highlighted the potential of PRF for soft tissue healing and regeneration.

Furthermore**, Srisurang et al., 2014** study detected earlier wound healing with mature soft tissue coverage only after 2 weeks and maintenance of bone dimensions after 1.5 and 3 months, in case of PRF compared to FGG. They also recommended the use of PRF for short term preservation of alveolar ridge, as in cases of early implant placement.

AIM OF THE STUDY

Our Randomized Controlled clinical Trial (RCT) aimed to evaluate the effect of platelet rich fibrin (PRF) versus free gingival graft (FGG) in preservation of soft tissue volume of extraction socket/ alveolar ridge, in terms of the soft tissue profile for assessment of the soft tissue changes, after atraumatic tooth extraction and socket preservation procedure **(Barone et al., 2013).**

MATERIALS AND METHODS

Study setting

This randomized controlled clinical trial study was conducted in Department of Periodontology clinic, Faculty of Dentistry, Cairo University-Egypt. Post graduate Periodontology clinic 1st floor old section. Sirona dental units with light-emitting diodes (LED) light.

Study design

The present randomized controlled clinical trial included two parallel groups of patients with non – restorable teeth scheduled for extraction, where each group received a single treatment. Equal randomization for the participants was performed with equal probabilities for each intervention (1:1 allocation).

Sample size

Based on a previous study by **Karaca et al.** (Karaca *et al.*, 2015), the difference between the 2 groups in crestal bone level change is 1±0.8mm. Using power 80% and 5% significance level we

needed to study 11 patients in each group. This number was increased to a sample size of 13 in each group to compensate for losses during follow up (20% more than the calculated).

Sample size calculation was achieved using PS: Power and Sample Size Calculation Software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA).

Eligibility Criteria:

Inclusion Criteria

- Age range 25-40 years.
- Non- restorable teeth indicated for extraction.
- Good general health.
- Intact facial and lingual plates of bone, without infection or pathosis.

Exclusion Criteria

- Presence of uncontrolled Systemic disease eg: diabetes, bone disease or the use of medicines that interfere with bone metabolism, history of head and neck radiotherapy.
- Presence of periodontal and/or periapical infection.
- Heavy smokers (>10 cigarettes per day).
- Poor oral hygiene (non-compliant patients).
- Pregnancy or lactation in females.
- Concomitant participation in another trial.
- Bone disease or the use of medicines that interfere with bone metabolism.
- History of head and neck radiotherapy.
- Presence of dehiscence or fenestration on the bony walls of the socket.

Randomization

All patients who fulfilled the inclusion criteria as well as provided an informed consent for participation were randomized.

Allocation sequence was generated using computer-generated random numbers; List was created on https://www.random.org/, the patients were randomly classified into either group A (intervention) where PRF was used, or group B (control) where Free Gingival graft was used.

The randomly generated numbers were written in small folded opaque papers inserted into opaque envelopes. Principle investigator enrolled the participants & received the sealed envelope that contains the procedure to be performed.

Interventions

Preoperative measures for both groups (T0):

- Phase I therapy (Supragingival scaling, subgingival debridement and oral hygiene instructions) has been applied for the two groups before any surgical procedures.
- 4 weeks later both groups were examined to determine patient's compliance with oral hygiene procedures (tooth brushing twice daily and chlorhexidine HCL 0.12% mouthwash twice/day).
- Radiographic measurements for the Crestal bone level were determined through CBCT at baseline.
- Impressions were taken for study cast as well as for measuring the soft tissue profile at baseline.

Surgical phase (T1):

- The same operator performed all procedures under local anesthesia (4% articaine with

1/200 000 adrenaline Solution, using a local infiltration technique.

- Atraumatic extraction for the non- restorable tooth was performed using periotome.
- Once the tooth/root was luxated, a dental forcep was used for pulling the tooth out of the socket without harming the socket walls.
- The socket was completely debrided using surgical bone curette, and appropriate irrigation for the socket was performed.

Intervention for test group (Group A):

- **PRF preparation and placement:** The PRF was prepared immediately just before placement at the surgical site.
- 5 ml of whole venous blood was collected and obtained in 10 ml glass or glass coated plastic sterile tubes without an anticoagulant and immediately spun at 2,700-3,000 revolutions per minute (rpm) for 10-12 min in a centrifuge tube**.**
- The blood was then settled into three layers, which are upper clear colored cellular plasma layer, Middle fraction containing the fibrin clot & Lower red layer containing RBCs, as shown in **Figure (1)**.
- The middle layer with the puffy coat of the lower layer was then cut and shaped as desired to be used as a PRF plug and membrane.
- PRF was prepared in the form of a membrane by squeezing out the fluids present in the fibrin clot. This was done by gently pressing the plug on a sterile metal plate of the PFR box.
- The centrifuge machine was put close to the operatory site and the time was limited between the preparation of PRF and its placement to create maximum regenerative potential.
- After placement of the PRF, criss- cross suture was performed for stabilizing the PRF membrane, as shown in **Figure (2)**.

Figure (1) Platelet-Rich Fibrin (PRF) obtained from the PRF glass tube after centrifugation

Figure (2) PRF membrane sutured in place covering the extraction socket immediately post extraction

Intervention for control group (Group B):

Preparation of donor site:

– A Free gingival graft was obtained from the palate using 15c scalpels. Four incisions giving a square-shaped graft, as shown in **Figure (3A)**.

– Shaping & contouring of the obtained graft was performed, as shown in **Figure (3B)**.

The free gingival graft covered the extraction socket, with the tails of the graft tucked into the facial and lingual pouches **Figure (3C)**. The tucked ends of the grafts were previously de-epithelialized by a lancette.

Figure (3A) Palatal incision for free gingival graft

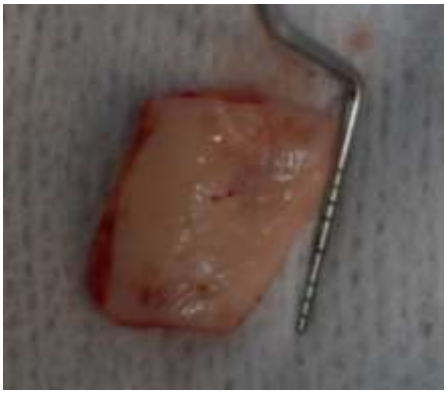

Figure (3B) Showing the dimensions of the obtained graft using periodontal probe

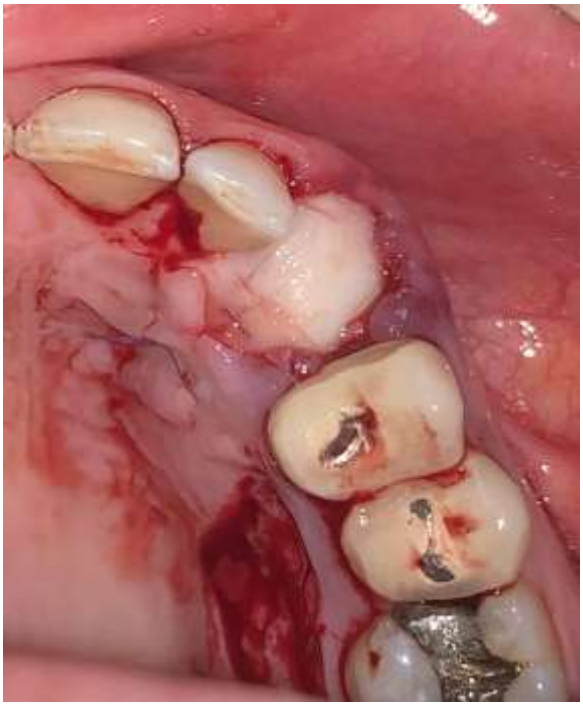

Figure (3C) FGG covering the extraction socket

Follow-up after 6 months (F2):

– Impressions were taken, and casts were obtained accordingly. Casts were scanned by optical scanner, shown in **Figure (4A)** to detect and measure changes in the soft tissue profile of the participants. The soft tissue profile changes were measured as the differences between the optically scanned postoperative and preoperative casts by superimposition, shown in **Figure (4B)** .

Figure (4A) Optical scanning of diagnostic Casts by Medit T-Lab scanner

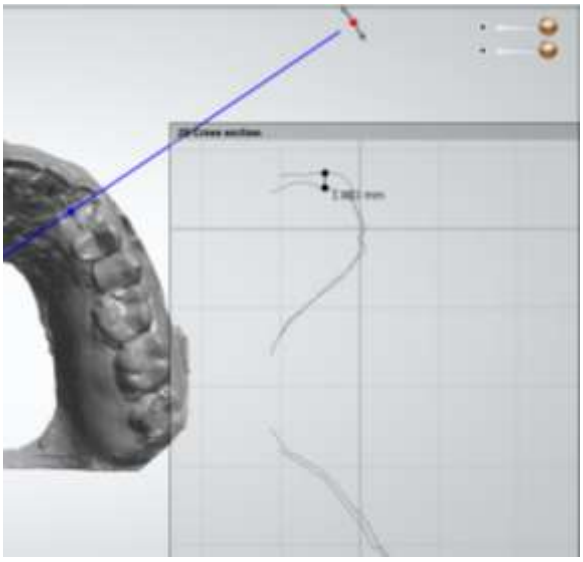

Figure (4B) Superimposition of Optically scanned pre and post operative casts to measure the changes in soft tissue profile

The trial protocol was published on www.clinicaltrials.gov protocol registration and results system with an identifier ID: NCT03628170. The research protocol, informed consents and biological sample collection request were approved by the Ethics Committee of Scientific Research, Faculty of Dentistry, Cairo University.

Statistical analysis

Data presented as mean and standard deviation (SD). Data explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Soft tissue profile showed normal distribution, so independent t-test used to compare between tested groups.

The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.

RESULTS

Insignificant difference on mean Soft tissue profile (mm) changes between group A (PRF) and group B (FGG) was found, at p=0.528, as shown below in **Table (1),** illustrated by **Figure (5).**

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Soft tissue profile (mm)	1.7	0.7	2.0	0.6	0.528 NS

Table (1) Mean and SD for Soft tissue profile (mm) for different tested groups

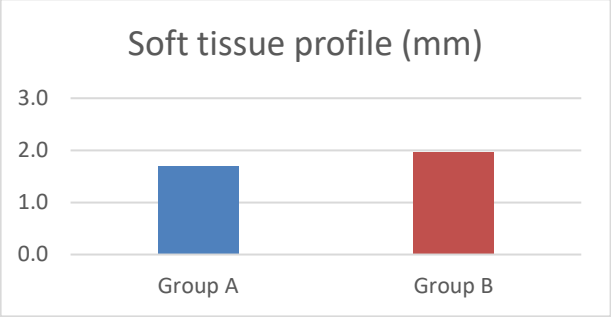

Figure (5) Bar chart showing the mean Soft tissue profile (mm) for different tested group

DISCUSSION

The current study was conducted to evaluate the effect of platelet rich fibrin (PRF) versus free gingival graft (FGG) in preservation of hard and soft tissue volume of extraction socket/ alveolar ridge, in terms of the soft tissue profile for assessment of the soft tissue changes, after atraumatic tooth extraction and socket preservation procedure.

Free Gingival Graft was used as a control in this study as it has been considered by many studies to be a successful material for alveolar socket preservation postextraction, it is considered as a gold standard for alveolar ridge preservation. **Thalmair et al., 2013** observed reduced postoperative shrinkage buccally on using FGG alone or in conjunction with bone graft (xenograft) to preserve the extraction sockets where it was concluded that using FGG for preservation of extraction sockets is a simple and cheap alternative that maintains the alveolar ridge dimensions and reduce the soft tissue volumetric changes, which might eliminate the need for further ridge augmentation during the prosthetic phase.

Platelet rich fibrin (PRF) was chosen among all other APC preparations as it has been proven to be a rich source of growth factors as vascular endothelial growth factor (VEGF), transforming growth factor β−1 (TGFβ−1) and platelet derived growth factor (PDGF), which are all bound within the fibrin matrix leading to sustained prolonged release of integrated growth factors through clot maturation and reorganization, which might continue as long as 10-14 days. PRF is a second generation APC that enhances angiogenesis and hence the whole tissue healing process. PRF is considered as a simple preparation that improves soft tissue healing as well as enhances bone formation **(Srisurang et al., 2014; Clark et al., 2018; Vitor et al., 2019)**.

In co-ordnance with **Flügge et al. 2015a** randomized controlled pilot study, only healthy, non-smoker patients free from any systemic diseases were selected for our current study to exclude any confounding factor that may affect the healing process; with exclusion of patients having uncontrolled systemic diseases, such as diabetes, bone disease or the use of medicines that interfere with bone metabolism, history of head and neck radiotherapy. Also teeth displaying periodontal and/or periapical pathosis were excluded from the study; poor oral hygiene cases with active gingival/ periodontal inflammation, bleeding on probing, pus or attachment loss were

considered to be ineligible for our study (Vitor *et al.*, 2019).

Impressions were taken preoperatively and postoperatively after 6 months to obtain study casts, by which these casts were then analyzed by Optical scanning to measure the changes in soft tissue profile after different socket preservation techniques. This technique was believed to give accurate measurements in terms of volumetric changes in soft tissue profile, this was supported by **Thalmair et al., 2013,** where it was proven that optical scanning is an accurate, highly reproducible method for the soft tissue profile changes assessment, with a low possibility of error. Additionally, in a systematic review by **Tavelli et al., 2021,** it was found that optical scanning is the only way for assessment of volumetric changes rather than linear changes, which can be assessed through many other methods as trans gingival probing.

Mean Soft tissue Profile changes in millimeters showed statistically insignificant difference between the intervention (PRF) group and the control (FGG) group, at p=0.528. This may support the use of A-PRF as a non invasive approach instead of harvesting free gingival graft.

Additionally, sockets with dehiscence or fenestration of facial bony walls at baseline, were not included in our randomized controlled clinical trial, as they were found to show higher rates of bone resorption and dimensional changes, compared to sockets which were found intact at baseline assessment. Sockets with dehiscence showed three times more bone height loss than intact ones, as well as fenestrated sockets showed up to six times more bone height loss than intact sockets (Chen, Chen and Darby, 2016).

CONCLUSION

PRF membrane can be used as an alternative to FGG in alveolar socket preservation, due to its important role in soft tissue healing as well as it improves the soft tissue profile with its known sustained release of growth factors that enhance the healing process.

CONFLICT OF INTEREST AND SOURCE OF FUNDING

Absence of any potential conflict of interest.

The study is self-funded by the principal (main) investigator.

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