ISRCTN86409051 https://doi.org/10.1186/ISRCTN86409051

The evaluation of the effect of platelet-rich fibrin (PRF) and xenograft used for the elimination of bone loss caused by periodontal (gum) infections on new bone formation in smokers and non-smokers

Submission date	Recruitment status	[ ] Prospectively registered
10/04/2021	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
26/04/2021	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
28/04/2021	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Periodontal (gum) disease is an infection of the tissues that hold your teeth in place. It's typically caused by poor brushing and flossing habits that allow plaque—a sticky film of bacteria—to build up on the teeth and harden.

It is known that smoking increases damage in periodontal tissues and negatively affects responses after surgical and periodontal procedures, periodontal regeneration in intra-bony defects (IBDs) and guided tissue regeneration in gingival recession.

Platelet rich fibrin (PRF) is a one-step method to obtain the platelet concentrates, or blood derivatives, that are needed to aid in the regeneration of soft tissue and bone, thereby creating a stable environment to perform dental procedures.

A xenograft is a type of bone or skin graft that is taken from a donor of another species. In the dental field, xenografts are usually porcine or bovine, meaning they come from pigs or cows. The grafts are cleaned, sterilized, and prepared for implantation into the human body. The most common grafts to be used in the dental industry are bone grafts. If a patient has bone loss due to disease, trauma, or missing teeth, a bone graft may be necessary before placing a dental implant.

This study aims to evaluate the effect of PRF and xenografts on bone formation in the treatment of periodontal intra-bony defects in smokers and non-smokers.

Who can participate?

Patients who had at least two intra-bony defects with radiological bone loss of 3 mm or more and 5 mm and more intra-bony defects with probing depth, who did not have systemic disease, who were not pregnant, and who did not use antibiotics in the last 6 months, were able to participate in the study.

What does the study involve?
Thirty chronic periodontitis patients were invited to study, but three patients did not continue treatment. Twelve smokers and fifteen non-smokers continued the treatment protocol. Initial treatment (scaling and root planning, polishing, occlusal adjustment) was performed in all patients. One month after the initial treatment, surgical operation was initiated according to the treatment protocol. Intra-bony defects in both groups were sub-grouped so that only PRF and PRF + xenograft was applied.

What are the possible benefits and risks of participating?
Possible results expected from the treatments applied to the patients were reduction of periodontal bone defects, elimination of periodontal disease, aesthetic gain and patient comfort.

Where is the study run from?
Dicle University Faculty of Dentistry, Department of Periodontology (Turkey)

When is the study starting and how long is it expected to run for?
November 2015 to September 2018

Who is funding the study?
The study was supported by the scientific research project unit of Dicle University (Turkey) with the project number DİŞ.16.004

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DİŞ.16.004

Study information

Scientific Title
The examination of the effects of PRF and xenograft on bone regeneration in the treatment of intra-bony defects in smokers and non-smokers

Study objectives
PRF / xenograft combination provides more new bone formation in the treatment of periodontal intra-bony defects in smokers and non-smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/12/2015, Dicle University Faculty of Dentistry Ethics Committee (Dicle Üniversitesi Diş Hekimliği Fakültesi, 21100, Sur, Diyarbakır, Turkey; +90 4122411017; ddekanlik@dicle.edu.tr), ref: 2015-29

Study design
Mono-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intra-bony defects caused by periodontal (gum) diseases

Interventions
Initial treatment was performed in all groups to ensure the formation of new bone in the intra-bone defects caused by periodontal infections in smokers and non-smokers. Grouping of patients was named as group 1 smoking patients and group 2 for non-smokers. Randomisation was by sealed envelope.
Group 1a was named if alone PRF was applied to the intra-bony defects in smoking patients, and for group 1b, the combination of PRF and xenograft was applied. In non-smokers, group 2a was named if alone PRF was applied to the intra-bony defect, and for group 2b, the combination of PRF and xenograft was applied. Initial treatment consisted of oral hygiene instructions, scaling and root planing, polishing, emergency restorations and occlusal adjustment. Surgical operation was initiated 4 weeks after the initial treatment. PRF was prepared before surgical operation. Venous blood taken from antecubital vein was transferred to the tube and placed in the

centrifuge device without losing time. Centrifugation was carried out for 10 minutes at 3000 rpm. After centrifugation, platelet-poor plasma and red blood cell layer were removed with a scissors. In order to obtain a fibrin of equal thickness, fibrin was placed in the PRF box.

After asepsis and antisepsis are provided by washing with 10% povidone-iodine solution inside the mouth, anesthesia of the surgical region was attained with a local anesthetic solution containing 1.8 ml of 2% lidocaine HCl epinephrine. A crevicular incision was made to extend to the mesial and distal of adjacent teeth of the teeth with the defect. No vertical incision was benefited due to aesthetic concerns. After the incision, the full thickness mucoperiosteal flap was performed and epithelial residues were removed. Flap thinning techniques were not used to avoid negative effects on flap healing. After the granulation tissues were removed, bleeding was controlled, and the defects were filled according to study design.

Some of the PRF clots were placed in the into one of the defects in the mouth and the remaining of PRF was used as a membrane to cover the defect. After the PRF was placed, the operation site was closed with a 3/0 silk suture. For another defect, the protocol described above was followed and part of the PRF clot in small pieces was placed to be combined with the graft material into the PRF Box. Combining PRF and graft material was inserted in defect site. The remaining PRF was placed on the defect region as a membrane and the site was sutured. So as to block post-op infection, amoxicillin + potassium clavulanate (1000 mg, 2x1000 mg/day), paracetamol (500 mg, 2x500 mg/day) were medicated for a period of 7 days and were rinsed 0.2% solution of chlorhexidine digluconate for 2 weeks. After 10 days post-op, the sutures were removed. Radiographic and clinical measurements were recorded in the 3rd and 6th months after the flap operation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Probing depth (mm) was measured using a 0.5 mm diameter Williams periodontal probe at baseline, 1 month after initial treatment, the time of surgical operation, 3 months after surgical operation and 6 months after surgical operation
2. Radiological defect depth (mm) was measured on radiological images at baseline, 3 and 6 months after surgical operation

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
13/09/2018

Eligibility

Key inclusion criteria
Two intra-bony defects with a probing depth ≥5 mm, ≥ 3 mm radiographic defect depth, ≥ 3mm intra-bony defect depth established at the time of surgery

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
27

Key exclusion criteria
1. The existence of any systemic diseases
2. Using antibiotics/anti-inflammatory and/or antiaggregant agents at least 6 months before treatment
3. Pregnancy

Date of first enrolment
02/01/2016

Date of final enrolment
11/06/2017

Locations

Countries of recruitment
Türkiye

Study participating centre
Dicle University
Faculty of Dentistry
Department of Periodontology
Diyarbakır
Türkiye
21100

Sponsor information

Organisation
Dicle University

ROR
https://ror.org/0257dtg16

Funder(s)

Funder type
University/education

Funder Name
Dicle Üniversitesi

Alternative Name(s)
Dicle University

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Türkiye

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request