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The use of patient's own blood plasma derivative and palatal tissue graft in dental implant surgery

Submission date
22/05/2023

Recruitment status
No longer recruiting

Registration date
25/05/2023

Overall study status
Completed

Last Edited
24/05/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental implants are widely used as a treatment to replace missing teeth. The thickness and width of keratinized tissues determine the viability of implants over time, their stability in function and aesthetics. The aim of this study is to assess and compare the use of platelet-rich fibrin (PRF) and sub-epithelial connective tissue graft (SCTG) at improving the condition of peri-implant soft tissues and enhancing aesthetic outcomes.

Who can participate?
Patients aged 18 to 60 years with thin gingival (gum) biotype (less than 1 mm) who are undergoing dental implantation and soft tissue augmentation around dental implants

What does the study involve?
Participants are randomly allocated to one of two groups. Group I receive delayed dental implantation with SCTG and PRF membrane during the second-stage implant surgery while Group II receive delayed dental implantation with SCTG during the second-stage implant surgery. The researchers assess the width and thickness of keratinized tissue, aesthetics, gingival blood flow, wound healing and cytokines in the fluid around the implant.

What are the possible benefits and risks of participating?
There will be no immediate direct benefits or risks to those taking part. Risks may be associated with the use of SCTG where there is a risk of developing necrosis of graft or suppuration (pus discharge). To eliminate risks, monitoring is carried out in the postoperative period.

Where is the study run from?
S.D. Asfendyarov Kazakh National Medical University in Almaty (Kazakhstan)

When is the study starting and how long is it expected to run for?
November 2020 to January 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Azhibekov Aibek, azhibekov.a@kaznmu.kz
2. Dr Menchisheva Yuliya, menchisheva.y@kaznmu.kz

Contact information

Type(s)
Scientific

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Study information

Scientific Title
The use of platelet-rich fibrin in combination with sub-epithelial connective tissue graft in peri-implant soft tissue augmentation

Study objectives
The use of platelet-rich fibrin (PRF) and sub-epithelial connective tissue graft (SCTG) is an effective method in augmenting peri-implant soft tissue and improving gingival biotype and aesthetic outcomes which would help overcome the complications and increase patients' satisfaction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/05/2021, Research Ethics Committee of the Asfendiyarov Kazakh National Medical University (3rd floor, Tole bi str.92, Almaty, 050000, Kazakhstan; +8 (0)727 338 7024; lec. kaznmu@mail.ru), ref: 6(112)

Study design
Interventional single-blinded randomized parallel trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of gingival thickness in patients with thin gingiva biotype who undergoing dental implantation

Interventions
Patients aged between 18 and 60 years with single or multiple non-restorable teeth were selected according to inclusion and exclusion criteria. The patients were randomly assigned to two groups using the method of random numbers; Group I received delayed dental implantation with SCTG and PRF membrane during the second-stage implant surgery while Group II received delayed dental implantation with SCTG during the second-stage implant surgery.

After implant placement during second-stage implant surgery the SCTG that is de-epithelialized extraorally was harvested from the lateral part of the hard palate. Two horizontal and two vertical incisions are performed perpendicular to the mucosal surface, 1.0–1.5 mm deep. The mucosal defect on the donor part is closed with a collagen membrane and sutured. The graft is positioned on sterile gauze, moistened with a saline solution and de-epithelialized with a scalpel blade. The SCTG was put inside the vestibular pouch by mattress suture.

In Group I the PRF membrane was prepared, where 10 ml of blood was obtained from the vein and transferred to the free anticoagulant tube. The blood sample was centrifuged at 700 g for 8 min and then the resultant fibrin clot was compressed in the PRF box to obtain the PRF membrane which was then applied over the SCTG. The feature of the surgical procedure was the formation of the flap and the shift of the initial keratinized tissues to the lingual side. The graft and PRF were stabilized with an absorbable suture (Vicryl 5-0).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Width of the keratinized tissue determined by measuring the distance between the mucogingival junction (MGJ) and free gingiva using a graduated periodontal probe at baseline, 3 and 6 months after the surgical procedure
2. Thickness measured by the cone-beam computed tomography (CBCT) with Ez3D-1 software (Vatech, Korea) before and 3, 6 months after the surgical procedure. The measurement of the thickness of mucous for determination of biotype was provided according to the following steps: before the examination in the vestibule site of the oral cavity dental cotton swabs were put, measurements are carried out in the frontal and sagittal dimensions in areas corresponding to the vestibular cortical plates of the root of the examined tooth, in the projection of the central axis of the tooth, from the top of the cortical plate to the mucogingival junction.

Key secondary outcome(s))
1. Wound healing (epithelialization) measured using a cytological analysis at baseline, 3, 5, 7, and 10 days
2. Local immunity measured using a sandwich enzyme-linked immunosorbent assay (ELISA) for determination of the concentration of pro- and anti-inflammatory cytokines (IL-1β, TNFα and IL-4) in the peri-implant cervicular fluid at baseline, 1, 7 and 30 days

3. Gingival blood flow measured using a laser Doppler flowmetry (LDF) at baseline,1, 7 and 14 days
4. Esthetic result (mesial and distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies, soft tissue color, and texture) measured using a Pink esthetic score (PES) at 6 months after the prosthetic phase

Completion date
03/01/2023

Eligibility

Key inclusion criteria
1. Aged 18-60 years
2. Patients with single or multiple non-restorable teeth
3. Thin biotype of gingiva
4. Sufficient bone of alveolar ridge
5. Absence of untreated periodontal disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Pregnancy
2. Systemic diseases
3. Thick biotype
4. Insufficient bone

Date of first enrolment
01/10/2021

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
Kazakhstan

Study participating centre
Asfendyarov Kazakh National Medical University
Tole bi 92
Almaty
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Sponsor information

Organisation
Kazakh National Medical University

ROR
https://ror.org/05pc6w891

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a non-publicity available repository of Asfendiyarov Kazakh National Medical University.
The data will be stored:
1. The thickness and width of keratinized tissue before in mm
2. The scores of PES
3. The level of TNF-α, IL-1β and IL-4 in pg/ml
4. The blood flux values according to LDF in A.U. (arbitrary unit)
5. Age/sex/nationality
The process for requesting access: via a principal investigator mail request (Dr Azhibekov Aibek,

azhibekov.a@kaznmu.kz)
Dates of availability: until 03/01/2025
Consent from participants was obtained in written form in Kazakh language
Comments on data anonymization: after enrollment, each patient received a unique identification number, in which all data were recorded accordingly. Personal identifying information provided by participants was separated and modified from the data, thus, outcome assessors and data analysts were blinded and had no access to information that could identify individual participants during or after data collection.

IPD sharing plan summary

Stored in non-publicly available repository