

3D-printable biopolymers and their use in dentistry

Submission date 02/03/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/04/2026	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

All the patients enrolled in the study had a financial convenience , since .
The study was conducted in and lasted from June 2023 to July 2023.
No funds were received for the trial and the responsible was the adjunct professor

Background and study aims

The goal of this clinical study is to assess how well 3D printed biopolymers, mixed with materials that promote bone growth (beta-tricalcium phosphate and hydroxyapatite), work for closing soft tissues after having a tooth removed.

Who can participate?

The study was opened to all patients requiring a tooth extraction

What does the study involve?

The procedure involved removing the tooth, and then randomly choosing whether to close the socket using a 3D printed disk made from two types of biodegradable materials: polylactic acid and polycaprolactone. Both materials were mixed with synthetic ceramic substances that promote bone growth, specifically 10% hydroxyapatite and 20% beta tricalcium phosphate, respectively.

What are the possible benefits and risks of participating?

The procedure was done free of charge.
No risks

Where is the study run from?

Trisakti University (Indonesia)

When is the study starting and how long is it expected to run for?

May 2023 to July 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Nicola De Angelis, n.deangelis74@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Nicola De Angelis

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

3D-printable biopolymers for socket preservation technique: soft tissues response. A randomized clinical trial.

Study objectives

Soft tissues response after tooth extraction is the same whether the socket is sealed by a polymeric 3D printed disk or is left open to heal

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 03/05/2023, Ethics Committee for Health Research Faculty of Dentistry, Universitas Trisakti (Jl. Kyai Tapa No.260 4, RT.4/RW.16, Jakarta, 11440, Indonesia; +62 21 566 3232; komisetikfkg@trisakti.ac.id), ref: 641/S3/KEPK/FKG/5/2023

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Soft tissues response following teeth extractions

Interventions

All the extractions were performed without flap elevation without any antibiotic prophylaxis. A careful cleaning of the socket was done in order to exclude the possible presence of inflammatory tissue, without grafting any additional bone substitute. Once tooth extraction was completed, the operator opened a sealed envelope containing the result of the randomization in order to include the patient in one of the following study groups:

TEST 1: a 3D printed disk of poli-D-lactic acid with 10% of hydroxyapatite had to be trimmed inside the gingival margin and ensured with a crossed mattress suture.

TEST 2: a 3D printed disk of poli- ϵ caprolactone with 20% of β -tricalcium phosphate had to be trimmed inside the gingival margin and ensured with a crossed mattress suture.

CONTROL: extraction left to heal without any graft materials. Only a collagen sponge was used in case of excessive bleeding.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Soft tissues closure was measured at the baseline and 30 days after the procedure with intraoral photographs

Key secondary outcome(s)

Bone formation was measured at the baseline at 30 days after the procedure with intra-oral periapical X-rays

Completion date

31/07/2023

Eligibility

Key inclusion criteria

1. Medically healthy
2. No assumption of bifosphonates
3. No or light – medium smokers (maximum 10 cigarettes/day)
4. Requiring a tooth extraction

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Total final enrolment

39

Key exclusion criteria

1. Pregnancy and lactation
2. Patients with signs of acute infection at the extraction site

Date of first enrolment

01/06/2023

Date of final enrolment

30/06/2023

Locations

Countries of recruitment

Indonesia

Study participating centre

Trisakti University Dental Department

Jakarta

Indonesia

11440

Sponsor information

Organisation

Trisakti University

ROR

<https://ror.org/019fnr381>

Organisation

University of Genoa

ROR

<https://ror.org/0107c5v14>

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 study will be available upon request from Nicola De Angelis n. deangelis74@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/10/2024	08/04/2026	Yes	No
Participant information sheet			04/03/2024	No	Yes
Protocol file	version 1		04/03/2024	No	No