

# 3D-printable biopolymers and their use in dentistry

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

## 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

### ORCID ID

<https://orcid.org/0000-0001-8622-4328>

### Contact details

Largo R. benzi 10

Genoa

Italy

16121

+39 3474188180

nicolaantonio.deangelis@edu.unige.it

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

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-  $\epsilon$  caprolactone with 20% of  $\beta$ -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**

Adult

**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 amiable 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?
<a href="#">Participant information sheet</a>			04/03/2024	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1		04/03/2024	No	No