# Is a new gum replacement material from a pig as effective as a person's own gum taken from the palate placed around dental implants?

Submission date	Recruitment status	Prospectively registered
25/09/2019	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
22/01/2020	Completed	Results
Last Edited	<b>Condition category</b> Oral Health	Individual participant data
22/01/2020		Record updated in last year

## Plain English summary of protocol

Background and study aims

Dental implants offer a reliable treatment in the replacement of missing teeth. A well-integrated titanium implant serves as an artificial root into which a prosthetic crown can then be fitted. The successful integration of an implant depends, among other things, on healthy surrounding soft tissues or mucosa. The oral mucosa, lining the mouth can be classed as either keratinised or non-keratinised. Keratinised mucosa is more resilient and provides a stable cuff of tissue around the dental implant. This helps the patient to maintain good oral hygiene and creates an aesthetic profile that mirrors the natural tooth-tissue relationship. The soft tissue surrounding the implant may become inflamed as a result of poor and/or painful brushing and plaque accumulation. This condition is known as peri-implant mucositis. If left untreated, it could cause inflammatory bone loss around the implants called peri-implantitis and may ultimately lead to the premature failure of the implant.

Studies have shown that surgical reconstruction of the peri-implant keratinised mucosa (PIKM) can prevent disease progression. In order to reconstruct the missing PIKM, various materials can be applied such as patient's own gum tissue from palate (autograft) or graft material from another species (xenograft). To date autograft has yielded the most reliable results and serves as "gold standard". However, the harvesting of a patient's own tissue can cause significant pain and discomfort. Further drawbacks include the limited amount of tissue available for harvesting and a compromised colour match at the recipient site as compared to the neighbouring soft tissue. Such disadvantages have led to an increased need for xenografts.

A recently developed xenogenic material derived from a pig tissue called mucoderm® has shown promising results in increasing PIKM width. The aim of this study is to test whether the mucoderm® works as successful as the own gum tissue to improve the width of PIKM. In addition, we compare the treatment time, pain, discomfort after the surgeries.

Who can participate?

Dental implant patients with insufficient gum width at the implant area

What does the study involve?

Participants will be randomly assigned to receive treatment as usual or treatment using the mucoderm® material.

What are the possible benefits and risks of participating?

Subjects would benefit from the increased PIKM as described to be a prerequisite for implant longevity. Side effects to include general post-operative surgical site effects such as pain, discomfort, minor bleeding and swelling (as usual side effects in such "out of study" interventions). In addition, the main aim of the study is to test a material and technique which may reduce these side effects.

Where is the study run from?

Department of Periodontology, Faculty of Dentistry, Semmelweis University, Hungary

When is the study starting and how long is it expected to run for? October 2018 to December 2020

Who is funding the study?

Department of Periodontology, Faculty of Dentistry, Semmelweis University, Hungary

Who is the main contact?
Dr Attila Horvath
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## Contact information

## Type(s)

Scientific

#### Contact name

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

P-2/2017

# Study information

#### Scientific Title

Comparison of epithelized connective tissue graft and porcine dermal matrix (mucoderm®) to increase the amount of peri-implant soft tissue. Randomised controlled clinical trial

#### **Acronym**

PIKM increase

### **Study objectives**

New porcine-derived xenograft (mucoderm®) may be equally effective as the gold standard epithelized connective tissue autograft to increase peri-implant keratinised mucosa (PIKM) with the reduction of the inherent risks and side effects of autograft harvest

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 13/11/2019, Semmelweis University Regional and Institutional Committee of Science and Research Ethics (Üllői út 93, Budapest 1091, Hungary; +36 2157300 ext. 53513; sotonyi. peter@med.semmelweis-univ.hu), ref: 223/2017

### Study design

Single centre interventional randomised single masked controlled clinical trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Peri-implant mucositis, peri-implantitis

#### Interventions

Subjects were divided into control and test groups for both the upper and lower jaws. The total duration of the study is one year.

#### Subject Groups:

- 1. Upper jaw test group (Group 1): PIKM augmented with mucoderm®
- 2. Upper jaw control (Group 2) group: PIKM augmented with ECTG
- 3. Lower jaw test group (Group 3): PIKM augmented with a combination of mucoderm® and ECTG strip
- 4. Lower jaw control group (Group 4): PIKM augmented with ECTG

Treatment Summary:

#### Group1:

A split-thickness flap is elevated apically at the mucogingival junction (MGJ) and anchored to the periosteum with continuous sutures. The recipient site is exposed and the mucoderm® is trimmed and sutured to the underlying periosteum using two different suture techniques (a mixture of internal and external horizontal mattress sutures) to ensure tight contact and avoid blood clot formation between the recipient site and the mucoderm®.

#### Group 2:

Same as in group 1 but instead of xenograft, an ECTG autograft is harvested from the hard palate (donor site) which is restored using a collagen matrix (lyostypt®) and stabilized by continuous sutures.

#### Group 3:

Same as in Group 1, but apically to the mucoderm® a narrow ECTG strip (2mm width) is sutured to the periosteum.

#### Group 4:

Same as in group 2

#### Details of randomization process:

Block randomization technique

The control group and test group are assigned the letters T (21 test) and C (12 control), respectively. These 24 letters (papers) will be placed in opaque envelops and sealed right after. All these sealed envelopes will be placed in an opaque box. On the day of each surgery a third party (independent of study) pulls blindly and opens one sealed opaque envelop. Therefore, the random assignment will be revealed.

The same randomization method will be used in both jaw bones, respectively

### Intervention Type

Procedure/Surgery

### Primary outcome(s)

PIKM width (PIKM-W) in mm, measured at baseline, 1, 3, 6, 9, 12 months

## Key secondary outcome(s))

- 1. PIKM thickness (PIKM-T) in mm, measured at baseline, 1, 3, 6, 9, 12 months
- 2. Pocket Probing Depths (PPD) measured at baseline, 3, 6, 9, 12 months
- 3. Plaque Index (PI) measured at baseline, 1, 3, 6, 9, 12 months
- 4. Bleeding on Probing (BoP) measured at baseline, 1, 6, 9, 12 months
- 5. Full mouth plaque score (FMPS) measured at baseline
- 6. Patient-centred outcomes:
- 6.1 Postoperative pain measured by VAS at 2 weeks
- 6.2 Cumulative painkillers taken post-operatively at 2 weeks
- 6.3 Surgical time

## Completion date

31/12/2020

# **Eligibility**

## Key inclusion criteria

- 1. Patients who underwent implant surgery restored with dental implant-supported prosthesis, but PIKM is either absent or PIKM-W is less than 2mm
- 2. Patients prior to implant surgical procedure, but keratinised mucosa was insufficient at the edentulous area

### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Αll

#### Key exclusion criteria

- 1. Elective oral surgical intervention is contraindicated. In particular patients with uncontrolled or poorly controlled diabetes should be excluded.
- 2. Uncontrolled or untreated periodontal disease
- 3. Smoker
- 4. Infections or recent surgical procedures within 30 days of study initiation
- 5. Pregnant or lactating
- 6. Chronic treatment with any medication known to affect oral status (e.g., phenytoin, dihydropyridine, calcium antagonists, cyclosporine)
- 7. Radiotherapy or chemotherapy in the past 12 months prior to surgery
- 8. HIV or hepatitis
- 9. Physical handicaps that would interfere with the ability to perform adequate oral hygiene
- 10. Any investigational drug within 30 days of study initiation
- 11. Alcoholism or chronically drug abuse causing systemic compromisation
- 12. Severe bruxism or clenching habits

#### Date of first enrolment

10/01/2018

#### Date of final enrolment

31/12/2019

## **Locations**

#### Countries of recruitment

Hungary

### Study participating centre

Department of Periodontology, Faculty of Dentistry, Semmelweis University

Szentkiralyi utca 47

# Sponsor information

## Organisation

Department of Periodontology, Faculty of Dentistry, Semmelweis University

# Funder(s)

## Funder type

University/education

#### **Funder Name**

Department of Periodontology, Faculty of Dentistry, Semmelweis University

## **Results and Publications**

### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary

Other

### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes