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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
25/09/2019

Recruitment status
No longer recruiting

Registration date
22/01/2020

Overall study status
Completed

Last Edited
22/01/2020

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 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

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
All

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
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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