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# Treatment of periodontitis using a surgical regenerative therapy

**Submission date**
14/02/2019

**Recruitment status**
No longer recruiting

**Registration date**
21/02/2019

**Overall study status**
Completed

**Last Edited**
24/09/2021

**Condition category**
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Periodontitis is a chronic destructive inflammatory disease of the supporting tissues of the teeth. The inflammation of a periodontal tissues results in periodontal pocket formation and bone loss, and the ultimate result of the untreated disease is tooth loss. Enamel matrix proteins are secreted by ameloblasts and serve as important regulators of enamel mineralization. The periodontal tissue regeneration by means EMD is based on mimic the process that takes place during the development of the nascent root and periodontal tissue. The discovery of the presence of the enamel matrix layer between the peripheral dentin and the developing cementum, together with the capability of enamel matrix proteins to induce acellular cementum. Periodontal ligament, and alveolar bone formation, has provided the fundamental concept for enamel matrix derivative-supported tissue engineering in regenerative periodontal therapy. Regenerative periodontal surgery with EMD has been demonstrated to offer an additional benefit in terms of CAL gains and PD reduction respect to papilla preservation flaps alone. A consistent amount of evidence has indicated that regenerative techniques predictably show superior results than conservative approaches in the treatment of intrabony defects. Horizontal bone loss represents the least predictable periodontal defect type in the regenerative approaches and it is an unsolved challenge for clinicians. Currently used regenerative procedures are not routinely applicable to this type of lesion and there are only experimental studies in animals or case reports in humans showing unpredictable results. Based on the properties of EMD in actively stimulating periodontal ligament mesenchymal cells, it is possible to hypothesize that the use of EMD in suprabony defects could lead to better clinical results.

The aim of this study is to evaluate supra-bony defects healing ( i.e. defects displaying a predominantly horizontal pattern of bone loss) treated with an association of open flap debridement (OFD) and EMD respect to OFD alone after 12 months follow up period.

Who can participate?
Patients suffering from chronic periodontitis, age ≥ 18 years old, with suprabony defects with predominantly horizontal bone loss pattern in minimum 2 and maximum 7 adjacent teeth (teeth 1.5-2.5 or 3.5-4.5), in the mandible or maxilla, with PD≥6mm, at minimum one out of six examinated sites of each tooth; defects with infrabony component ≤ 2mm.

What does the study involve?
At the initial moment and 12 months post-operative, the following parameters were clinically recorded FMPS, FMBS, CAL, PD, REC at 6 sites/tooth. Gingival thickness, early wound healing index (EHI - Wachtel et al., 2003) was also recorded. The surgical procedure involves the procedure of modified or simplified papillary preservation, depending on the interproximal width. Intraoperative measurements: CEJ-BD, BC-BD, the infrabony component of the defect. A mucoperiostal flap extended at least one tooth mesially and distally from the defect was raised, the defects was debrided with Gracey curettes, manual and ultrasonic SRP was performed. EMD was applied to the sites of the test group after 2 minutes of conditioning with the 24% EDTA gel, followed by saline solution rinse. EMDs was not applied to sites in the control group. After the flap was repositioned, the interdental papilla were sutured without tension with 5-0 monofilament non-resorbable sutures. Clinical measurements were repeated at 12 months.

What are the possible benefits and risks of participating?
The benefits include increased CAL gains and improvement in all secondary outcomes for the patients in the test group. There is no risk for the participants.

Where is the study run from?
The study was run from the Department of Periodontology of the Federico II University of Napoli, Italy.

When is the study starting and how long is it expected to run for?
The study started in January 2015 and ended in October 2017.

Who is funding the study?
The study has no sources of funding other than personal funding of the authors. Incidental costs were covered by the Federico II University of Napoli, Italy.

Who is the main contact?
Prof Dr Vincenzo Iorio Siciliano

# Contact information

### Type(s)
Scientific


### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
2/02/2019

# Study information

### Scientific Title
Clinical outcomes of supra-bony defects treated with access flap and enamel matrix derivative or access flap alone: a 12-months randomized controlled clinical study

### Acronym
EMD-Suprabony

### Study objectives
There will be statistically significant differences between supra-bony defects healing after treatment of chronic periodontis using either open flap debridement treatment alone or open flap debridement treatment and enamel matrix derivative.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 02/02/2015, Commission on Research Ethics of the Victor Babes University of Medicine and Pharmacy Timisoara (Piata Eftimie Murgu 2A, 300041 Timisoara, ROMANIA (EU); 0040-256-466001; esanda2000@yahoo.com), ref: 03.

### Study design
Randomized control clinical trial.

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet
See additional files (Italian)

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

## Interventions
Depending on the mesio-distal width of the interproximal space, two different incision techniques will be selected to access the intrabony defect area. The modified papilla preservation technique (MMPT) will be used at sites with an interproximal width > 2 mm whereas the simplified papilla preservation technique (SPPT) will be applied at sites with an interproximal width ≤ 2 mm. A mucoperiosteal flap will be elevated and extended at least one tooth mesially and distally of the intrabony defect. Vertical releasing incisions, if required, will be performed. Following flap elevation, the granulation tissue will be removed by means of Gracey metal curettes. At this time point, scaling and root-planing will be performed combining the use of metal curettes and power-driven instrumentation without eliminate periodontal fibers.

The patients will be randomly assigned to one of the two experimental procedures by opening a sealed envelope. At test sites, an enamel matrix derivative (EMD) will be applied following root conditioning for 2 min with a 24% EDTA gel and rinsing with sterile saline solution according to manufacturer's instructions. At control sites the EMD will be not used. After flap repositioning, a tension-free primary closure of the interdental papillae will be achieved using a 5-0 monofilament non resorbable suturing material.

All subjects were recalled after 2 and 4 weeks and after 3, 6, 9 and 12 months for professional maintenance care. After 12 months, a follow-up examination was performed.

## Intervention Type
Procedure/Surgery

## Primary outcome measure
Clinical attachement level (CAL) will be measured using the distance from cemento-enamel junction (CEJ), to the bottom of the pocket at six sites per tooth at baseline and after the 12-months follow-up period.

## Secondary outcome measures
1. The total amount of bacteria in the mouth will be measured using the full Mouth Plaque Score (FMPS) at six sites per tooth at baseline and after the 12-months follow-up period.
2. Gingival bleeding will be measured using the full Mouth Bleeding Score (FMBS) at six sites per tooth at baseline and after the 12-months follow-up period.
3. Probing depth will be measured using the distance from the gingival margin to the bottom of the pocket at six sites per tooth at baseline and after the 12-months follow-up period.
4. Gingival recession will be measured using the distance from gingival margin to the cemento-enamel junction (CEJ) at six sites per tooth at baseline and after the 12-months follow-up period.
5. Gingival thickness (GT) in millimeters (mm) will be measured at a buccal location 1 mm apically to the bottom of the sulcus.
6. Probing bone level will be measured using the distance from the cemento-enamel junction (CEJ) to bone crest (BC).
7. Postoperative wound healing will be assessed by the early wound healing index (EHI) according to Wachtel et al 2003.

## Overall study start date

01/01/2015

### Completion date
30/10/2017

# Eligibility

### Key inclusion criteria
1. Patients suffering from chronic periodontitis;
2. Age ≥18 years old
3. Presence of supra-alveolar-type defects (i.e. defects displaying a predominantly horizontal pattern of bone loss) at a minimum of two adjacent teeth and a maximum of 7 adjacent teeth (FDI positions 15-25 or 35-45) in either the maxilla or the mandible with a PD ≥ 6 mm at a minimum on one site of examined teeth.
4. Intrabony defect with an intrabony component of < 2 mm;

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Twenty-six patients will be enrolled from Department of Periodontology, University of Naples "Federico II" ( 13 test and 13 control) and 26 from Department of Periodontology , University of Timisoara (13 test and 13 control).

### Total final enrolment
80

### Key exclusion criteria
1. Patients with systemic disease
2. Prolonged antibiotic treatment or anti-inflammatory treatment within 4 weeks prior to surgery
3. Pregnant or lactating
4. Tobacco smokers
5. Patients with FMPS and FMBS  25 % after completion of non surgical periodontal therapy recorded at six sites per tooth)
6. Intra-bony defects ≥ 2 mm or involving furcation involvement;
7. Presence of prothesis reconstructions
8. Multi-rooted teeth

### Date of first enrolment
01/03/2015

**Date of final enrolment**
31/12/2015

# Locations

**Countries of recruitment**
Italy

Romania

**Study participating centre**
**Department of Periodontology, University of Naples “Federico II”**
Via Sergio Pansini 5
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**Study participating centre**
**Department of Periodontology , Victor Babes University of Medicine and Pharmacy Timisoara**
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# Sponsor information

**Organisation**
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**Sponsor type**
University/education

**Website**
www.unina.it

**ROR**
https://ror.org/05290cv24

# Funder(s)

**Funder type**
University/education

**Funder Name**
Università degli Studi di Napoli Federico II

**Alternative Name(s)**
University of Naples Federico II, University of Naples, Federico II University of Naples, Università di Napoli, Università di Napoli Federico II, UNINA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Italy

# Results and Publications

**Publication and dissemination plan**
Journal of Periodontology, 2019

**Intention to publish date**
01/04/2019

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

**IPD sharing plan summary**
Stored in repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | 19/02/2019 | 22/02/2019 | No | Yes |
| Results article | | 19/06/2020 | 24/09/2021 | Yes | No |