A randomized, controlled clinical trial comparing treatment of buccal class II furcation defects in mandibular molars with a bovine derived xenograft (Tutodent® microchips [Tutogen, Neunkirchen am Brand, Germany]) in combination with a bovine derived collagen membrane (Tutodent® membrane [Tutogen, Neunkirchen am Brand, Germany] to treatment with a bovine derived xenograft (Tutodent® microchips [Tutogen, Neunkirchen am Brand, Germany]) alone.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30137

Source
ToetsingOnline

Brief title
Class II furcation treated with BDX plus collagen membrane or BDX alone

Condition

- Other condition

Synonym
Bone loss in between two roots of a molar, Furcation defect

Health condition

parodontologie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Tutogen Medical GmbH Industriestraße 6 91077 Neunkirchen am Brand Germany

Intervention

Keyword: bovine derived collagen membrane, bovine derived xenograft, controlled clinical trial, furcation class II therapy

Outcome measures

Primary outcome

Efficacy of therapy will be described by change of horizontal probing bone

level measurements (HPBL) as primary parameter.

Secondary outcome

Secondary study parameters are full-mouth plaque scores (FMPS), full-mouth

bleeding on probing scores (FMBS), site plaque score (SPS), site bleeding on

probing score (SBS), probing pocket depth (PPD), clinical attachment level

(CAL), recession (REC), horizontal probing depth (HPD), vertical probing bone level measurement (VPBL), vertical open bone level measurement (VOBL), and horizontal open bone level measurement (HOBL).

Study description

Background summary

Titel:
A randomized, controlled clinical trial comparing treatment of buccal class II furcation defects in mandibular molars with a bovine derived xenograft (Tutodent® microchips [Tutogen, Neunkirchen am Brand, Germany]) in combination with a bovine derived collagen membrane (Tutodent® membrane [Tutogen, Neunkirchen am Brand, Germany] to treatment with a bovine derived xenograft (Tutodent® microchips [Tutogen, Neunkirchen am Brand, Germany]) alone.

Background:
Molar teeth with furcation involvement respond less favorably to conventional periodontal therapy than molar teeth without furcation involvement or non-molar teeth. Therefore furcation involvement presents one of the greatest challenges in periodontal therapy. Available data from the literature suggests that treatment of mandibular class II furcation defects by means of a particulate graft material combined with GTR could result in additional clinical improvements compared to treatment with GTR alone.

Study objective

Up to now there are only very limited data from clinical studies available comparing treatment of mandibular class II furcation defects with various types of particulate graft materials in combination with GTR to the treatment with such a graft material alone. In particular, there are no data available from controlled clinical studies evaluating the healing of buccal mandibular class II furcation defects following treatment with Tutodent® microchips in combination with the Tutodent® membrane compared to treatment with Tutodent® microchips alone.
Moreover, it is unknown if the treatment outcome with Tutodent® microchips in combination with the Tutodent® membrane is superior to that with Tutodent® microchips alone.
Therefore, the aim of this study is to assess the effect of treatment of buccal class II furcation defects in mandibular molars with a bovine derived xenograft (Tutodent® microchips) in combination with a bovine derived collagen membrane (Tutodent® membrane to treatment with a bovine derived xenograft (Tutodent®

microchips) alone.

Study design

Multicentre study with an examiner-blinded parallel arm randomized design.

Intervention

Periodontal regenerative surgery. The furcation defects will be randomly treated with a bovine derived xenograft (Tutodent® microchips [Tutogen, Neunkirchen am Brand, Germany]) in combination with a bovine derived collagen membrane (Tutodent® membrane [Tutogen, Neunkirchen am Brand, Germany] or treated with a bovine derived xenograft (Tutodent® microchips [Tutogen, Neunkirchen am Brand, Germany]) alone.

Study burden and risks

The therapies used are standard therapies, therefore risks with participation, and benefit are not different for patients included in the study compared to patients treated in this way outside the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Periodontitis patients, diagnosed with chronic periodontitis, having reached at least the first re-evaluation time point after the initial phase of periodontal therapy.
All patients will have buccal class II furcation involvement in mandibular first or second molars.

Exclusion criteria

Beside the threshold levels decided for FMPS (25%) and FMBS (25%), patients will not be included in this study, (1) if they are systemically not healthy (that is, having any systemic condition that precludes periodontal surgery, or that might compromise wound healing), (2) if not diagnosed with chronic periodontitis, (3) treated with antibiotics within 3 months prior to surgery, (4) current smokers, and (5) involved in any other clinical trial. On a site level, the selected lower first or second molars will have (1) mandibular buccal class II furcation involvement (HPD > 3 mm), (2) proximal bone levels at or above the fornix of the furcation, and (3) a zone of keratinized tissue of at least 2 mm adjacent to the furcation defect, in order to provide coverage of the furcation entrance during surgery. If, (4) a root canal treatment was performed, the selected tooth must be asymptomatic and the root canal treatment must be without technical remarks, and (5) such a root canal treatment must be completed at least six months before the selected tooth is enrolled in the study. Teeth will be excluded from the study, if (1) buccal restorations extend to the furcation area in a way that the margins of these restorations are less than 1 mm away from the entrance of the furcation, (2) they have in addition lingual class II furcation involvement (HPD > 3 mm), (3) they are non-vital and have posts or screw retentive devices, (4) they are non-vital and are not endodontically treated, (5) furcation class III involvement is revealed during surgery, or (6) they have enamel projections into the furcation defect not being removable during surgery.

Study design

Design

Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12797.091.06