Coronally advanced flap combined with Geistlich Mucograft for the treatment of recession type defects: a randomized controlled clinical trial.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38205

Source
ToetsingOnline

Brief title
A prospective study on the Geistlich Mucograft collagen matrix.

Condition

- Other condition

Synonym
gingival recesssion, receding gums

Health condition

recessiedefecten van gebitselementen

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Geistlich Biomaterials,Geistlich Biomaterials;research contract

Intervention

Keyword: collagen, connective tissue, gingival recession, tissue regeneration

Outcome measures

Primary outcome

The primary outcome variable will be recession depth (RECd).

Secondary outcome

Secondary outcome variables will be percentage of defect coverage, recession

width (RECw), clinical attachment level (CAL), probing pocket depth (PPD), and

width of keratinized tissue (KTw).

Study description

Background summary

The main indications for root coverage procedures are esthetic / cosmetic demands, root sensitivity as well as changing the topography of the marginal soft tissue to facilitate plaque control (Wennström, et al. 2008).
The coronally advanced flap (CAF) combined with a free connective tissue graft (FCTG) is considered the *gold standard* for root coverage therapy. Consequently, alternative root coverage techniques are generally compared to CAF + FCTG and evaluated according to their ability to reduce recession and achieve root coverage (Oates, et al. 2003, Academy-Report 2005, Chambrone, et al. 2009). Moreover CAF + FCTG can be used for root coverage of a single tooth as well as multiple teeth, provided suitable donor tissue is available (Wennström, et al. 2008). However, especially the procedure to gain a FCTG from the area of the masticatory mucosa in the palate is rather technically demanding. Furthermore, the need for a second surgical site to harvest the graft tissue and resulted morbidity acts as limiting factors for this

technique. Moreover, the donor tissue from the palatal region may be insufficient for multiple recession treatments.
To overcome these drawbacks a xenogenic collagen matrix (CM; Mucograft® Collagen Matrix, Geistlich Pharma Ag, Wolhusen, Switzerland) has been developed. Recently, CAF + CM in comparison with a CAF + FCTG has been used in a randomized controlled clinical trial (RCT) (McGuire and Scheyer 2010).
McGuire and Scheyer (McGuire and Scheyer 2010) report that the residual recession depth at 6 and 12 months after surgery was significantly less for CAF + FCTG (after 6 months: $p < 0.01$, after 12 months: $p < 0.05$). Furthermore, percentage root coverage (RC) at 6 and 12 months after surgery was significantly more for CAF + FCTG (after 6 months: $p < 0.01$, after 12 months: $p < 0.05$). However, if only maxillary cases were considered (N=20) CAF+CM - and CAF+FCTG results were more nearly matched and became statistically indistinguishable at 1 year (91.1 ± 19.6% RC for CAF+CM and 99.2 ± 3.6% RC for CAF+FCTG; $p=0.125$). Similarly, when four problematic subjects were excluded from the overall study results - two graft trauma subjects, one methotrexate prescribed subject and one oncology radiation subject - overall RC draw even closer together (93.3 ± 14.7% RC for CAF+CM and 99.2 ± 3.7% RC for CAF+FCTG) and were, again, statistically indistinguishable at 1 year ($p=0.125$). Nonetheless, the variance for percentage root coverage in the CAF + CM group was still increased compared to the CAF + FCTG group. Moreover, as 95% confidence intervals for the mean recession depths and recession depth change were not provided, the transferability of the results is not clear.
Most recently, Cardaropoli et al. (Cardaropoli, et al. 2011) compared CAF+CM with CAF+FCTG in a RCT. In contrast to McGuire and Scheyer (McGuire and Scheyer 2010), Cardaropoli et al. (Cardaropoli, et al. 2011) report that residual recession depth (rRD) as well as percentage of RC at 12 months after surgery were not significantly different for CAF+CM as compared with CAF + FCTG (0.23 ± 0.47 mm rRD for CAF+CM and 0.09 ± 0.20 mm rRD for CAF+FCTG; 96.97 ± 6.74% RC for CAF+CM and 94.32 ± 11.68% RC for CAF+FCTG ; $p > 0.05$ using a paired t-test with 80% power and 0.05 level of significance). Finally, Cardaropoli et al. (Cardaropoli, et al. 2011) conclude that for CAF+CM recession reduction and percentage of root coverage are similar to those achieved by the use of CAF+FCTG.
Obviously, the currently available results for CAF+CM are not uniform. Therefore, in order to get more insight in patient and surgical site selection criteria the present study proposal aims to investigate CAF + CM compared to CAF + FCTG for single or multiple maxillary Miller class I and II recession defects (Miller 1985) in healthy patients.

Study objective

As stated before, the aim of this study is to investigate CAF + CM compared to CAF + FCTG for single or multiple maxillary Miller class I and II recession defects in healthy patients. In this way we can get more insight in patient and surgical site selection criteria.

Study design

This study is a RCT.

Enrollment in the study
Assessment of:
-FMPS (Full Mouth Plaque Score)
-FMBS (Full Mouth Bleeding Score)
-PPD (Probing Pocket Depth)
-PAL (Probing Attachment Level)
-RECd (Recession depth of the gingival margin)
-RECw (Recession width of the dehiscence defect)
-KTw (Keratinized Tissue width)
-DP (Digital Picture) to calculate percentage of defect coverage with digital image analysis software
-Radiograph (in order to classify the recession type defects according to Miller (Miller 1985)

Surgery (Baseline, BL)
Assessment of:
-FMPS
-FMBS
-PPD
-PAL
-RECd
-RECw
-KTw
-DP

At 6, 12, and 24 months after BL
Assessment of:
-FMPS
-FMBS
-PPD
-PAL
-RECd
-RECw
-KTw
-DP

Patients can be asked to come again for a clinical examination at 1 and/or 2 year(s) after BL.

Study burden and risks

Six, 12, and 24 months after surgery, a participant will have to visit a

dentist of our department for clinical measurements and a digital picture. Patients might be asked to visit the dentist again 3 and/or 5 years after surgery for the same clinical measurements. Because the clinical examination will not take very much time (0,5-1 hour) and the measurements are non-invasive, the burden associated with participation is not big.
As stated before, the collagen matrix (Geistlich Mucograft) used in the test group is a registered and approved product that has been used in general dental practice for some time. Therefore, there is no risk using this material in patients.

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

1. Patients have to present in good general health

2. Only non-smokers will be included
3. Good oral hygiene, i.e. full-mouth plaque score (FMPS) < 20%
4. Low levels of residual periodontal infection, i.e. full-mouth bleeding score (FMBS) < 20%
5. Only patients with optimal compliance will be enrolled in the study
6. Patients have to be willing to adhere to a strict Supportive Periodontal Therapy (SPT) protocol
7. Patients must be candidate for recession coverage presenting at least one, maximum 5 maxillary Miller class I or II recession type defect(s)

Exclusion criteria

1. Patients not fulfilling the inclusion criteria
2. Patient with uncontrolled or poorly controlled diabetes, using anticoagulants, presenting unstable or life-threatening conditions, or requiring antibiotic prophylaxis wil be exluded

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-01-2012

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	NL35662.091.11