10 December 2020

Research protocol

Effectiveness of Modified-free Gingival Graft for Treatment of Localized Gingival Recession Defects

NCT04718545

Principal investigator: Olivier Carcuac, DDS, PhD
The Sahlgrenska Academy at University of Gothenburg
Institute of Odontology
Department of Periodontology
Box 450
SE 405 30 Gothenburg
Sweden
Email: olivier.carcuac@odontologi.gu.se

Objectives

The aim of the present study is to evaluate, whether use of the modified free gingival graft (mod-FGG) technique improves treatment outcomes after surgical root coverage at mandibular incisors with gingival recession defects.

Background

Gingival recession defects (GRD), defined as displacement of the gingival margin apical to the cemento–enamel junction (CEJ) (1), are frequent clinical findings in the general population (2). According to Albandar et al. (3), who examined almost 10,000 adult subjects (aged 30-90 years) in the United States, gingival recessions (≥1 mm) were most prevalent at maxillary first molars and mandibular central incisors, noted in 35% of all individuals.

Indications for root coverage procedures include improved esthetics, reduction of root hypersensitivity and increase of the dimensions of keratinized tissue in order to facilitate infection control and prevent further progression of GRD. Numerous surgical techniques for root coverage have been suggested, with different degrees of success as assessed by the proportion of complete root coverage (CRC) (4,5). The influence of anatomical factors, such as a shallow vestibule, root prominence and limited width of keratinized tissue on treatment outcomes has been highlighted (6,7). Moreover, Zucchelli and coworkers (8) demonstrated that tooth location is crucial in predicting the level of final root coverage. The authors noted the least favourable outcomes at mandibular incisors. The lower success rate and lower predictability of root coverage at lower incisors, teeth with a high frequency of GRDs (3), may be explained by unfavorable anatomic conditions including marginal frenum attachment, high muscle pull and a shallow vestibule. These features are frequently encountered in the anterior area of the mandible, while they are rare in the maxillary anterior region (9).

Different surgical procedures aiming at root coverage have been described in the literature (11). Thus, coronally and laterally displaced flaps may be used alone or in combination with connective tissue grafts. Tunneling techniques were suggested, minimizing the need for surgical incisions (13). The free gingival graft (FGG) represents a different approach that includes the harvesting of connective and epithelial tissues (15). FGG was shown to be the most effective procedure for

gingival augmentation at sites with minimal amount of keratinized tissue (10), but was initially suggested to be used for root coverage (14-17). Great variability in terms of proportion of root coverage (range: 11% to 87%; mean: 63%) has been reported when applying this technique, however (12). One of the challenges may be the inadequate blood supply to the portion of the FGG placed on the exposed root surface. It is currently not understood, whether the blood supply to the FGG and, ultimately, treatment outcomes can be improved by modifying the surgical technique (mod-FGG).

Study design

Aim

The purpose of this randomized control trial is to compare clinical outcomes of surgical root coverage using either FGG or mod-FGG in the treatment of localized RT1 gingival recession defects at lower incisors.

Subjects and sample size

30 patients with localized gingival recession defects (RT1) at mandibular incisor will be included and randomly allocated to 2 treatment groups: a control group that will be treated with the conventional FGG technique and a test group that will be treated with the mod-FGG approach.

Inclusion criteria

Subjects with at ≥1 buccal RT1 gingival recession defect (18, 19, 20) at mandibular incisor will be invited considering the following inclusion criteria:

- age ≥18 years
- good general health
- non-smoker
- periodontally healthy
- low full-mouth plaque score
- thin phenotype

The tooth/teeth to be treated shall present with:

- probing pocket depth (PPD) ≤3 mm
- absence of excessive tooth mobility
- absence of cervical composite restorations or non-carious cervical lesions
- a shallow vestibule

Exclusion criteria

A subject meeting any of the following criteria will no be considered for inclusion:

- pregnancy
- smoking
- alcoholism
- para-functional habits
- poor oral hygiene
- excessive crowding or misalignment of teeth

Protocol

Randomization

Patients will be randomized to one of the two treatment groups with the use of a computer-generated table (ratio 1:1). Allocation will be concealed until the time of surgery.

Initial therapy, clinical measurements and patient-reported outcomes

Following an initial screening examination, all subjects will receive a session of prophylaxis including instructions in proper oral hygiene measures, scaling and professional tooth cleaning with the use of a rubber cup and a low abrasive polishing paste. Surgical treatment of the recession defects will not be scheduled until patients have demonstrated adequate standards of supragingival plaque control.

The following clinical measurements will be obtained 1 week prior to the surgical intervention and at the 1 year follow up-visit:

- gingival recession depth (RD): measured from the CEJ to the most apical extension of the soft-tissue margin

- probing depth (PD): measured from the soft- tissue margin to the bottom of the sulcus
- clinical attachment level (CAL): measured from the CEJ to the bottom of the sulcus.
- keratinized tissue height (KTH): measured from the soft- tissue margin to the mucogingival junction identifiable with Lugol® (J.Crow Company, New Ipswich, NH, USA) staining.

All measurements will be performed at the mid facial aspect of the treated teeth by means of a manual periodontal probe (PCP15, Hu-Friedy, Chicago, IL, USA) and will be rounded to the nearest millimeter. Measurements will be performed by a single examiner (OC). Full mouth plaque (FMPS) and bleeding (FMBS) scores will also be recorded using the percentage of total positive surfaces (four aspects per tooth).
Hypersensitivity and post-operative discomfort will be assessed through a visual analogue scale. The intake of pain medication and post-surgical swelling will also be recorded.

Root coverage procedures
All interventions will be performed by one experienced periodontist (OC). Mechanical instrumentation of root surfaces will be performed prior to surgery.

Test group - modified free gingival graft
The modified free gingival graft (mod-FGG) technique proposed by Carcuac & Derks (21) will be applied at test sites. The following steps will be included:

1 - <u>Preparation of the recipient site</u>: Initially, an intrasulcular incision will be made along the exposed root surface followed by 2 mm long horizontal incisions placed at the level of the CEJ. From each horizontal incision, vertical releasing incisions will then be placed in a diverging manner, extending well into the alveolar mucosa. A thin partial thickness flap will be created and excised, thereby delimiting the recipient area. The dimension of the recipient site will be accurately measured and reported on a foil template.

2 - <u>Preparation of the connective tissue pedicle flap</u>:

Apically to the recession defect, at a distance corresponding to the height of the exposed root surface, one horizontal incision and two vertical and slightly diverging, coronally directed incisions will be performed, delimiting the connective tissue pedicle flap. The flap will then be carefully dissected from the periosteum in a coronal direction. No dissection will be performed in the region directly apical to root surface, leaving the flap attach at its most coronal aspect. The connective tissue pedicle graft will then be flipped coronally and anchored on the exposed root surface through laterally placed bioabsorbable sutures.

3 - Harvesting of the free gingival graft:
The graft dimensions will be outlined in the palate adjacent to the premolars and first molar using the foil template created to match the recipient bed. A partial thickness graft consisting of epithelium and a thin layer of underlying connective tissue will be harvested, maintaining a distance of ≥2 mm to the maxillary teeth. The thickness of the graft will be about 1.5 mm. Following harvesting of the FGG, several drops of high-viscosity cyanoacrylate tissue adhesive will be applied to the palatal wound before covering it with a porcine-derived collagen sponge. The sponge will be stabilized by crossed sutures.

4 - Placement of the graft:
The FGG will be adapted to the recipient site and anchored to the periosteum by means of simple interrupted sutures using a 6/0 non-resorbable monofilament. Suturing will be continued along the lateral borders of the graft until complete stability of the graft is achieved. Vertically suspended crossed sutures will be placed, when needed, to achieve a slight compression of the graft to the recipient site.

Control group - traditional free gingival graft
The same surgical approach as outline for the test group with the exception of the connective tissue pedicle flap will be performed at control sites.

Data Analysis

Statistical analysis
Continuous data will be expressed as mean ±SD. Student's t-test will be used to evaluate changes of RD, PD, CAL and KTH as well as patient reported measures of

discomfort in test and control groups. Pearson's chi-square test will be used to compare CRC (categorical data). Regression analysis will be used to evaluate the correlation between reduction of RD to baseline RD and other potential confounding factors.

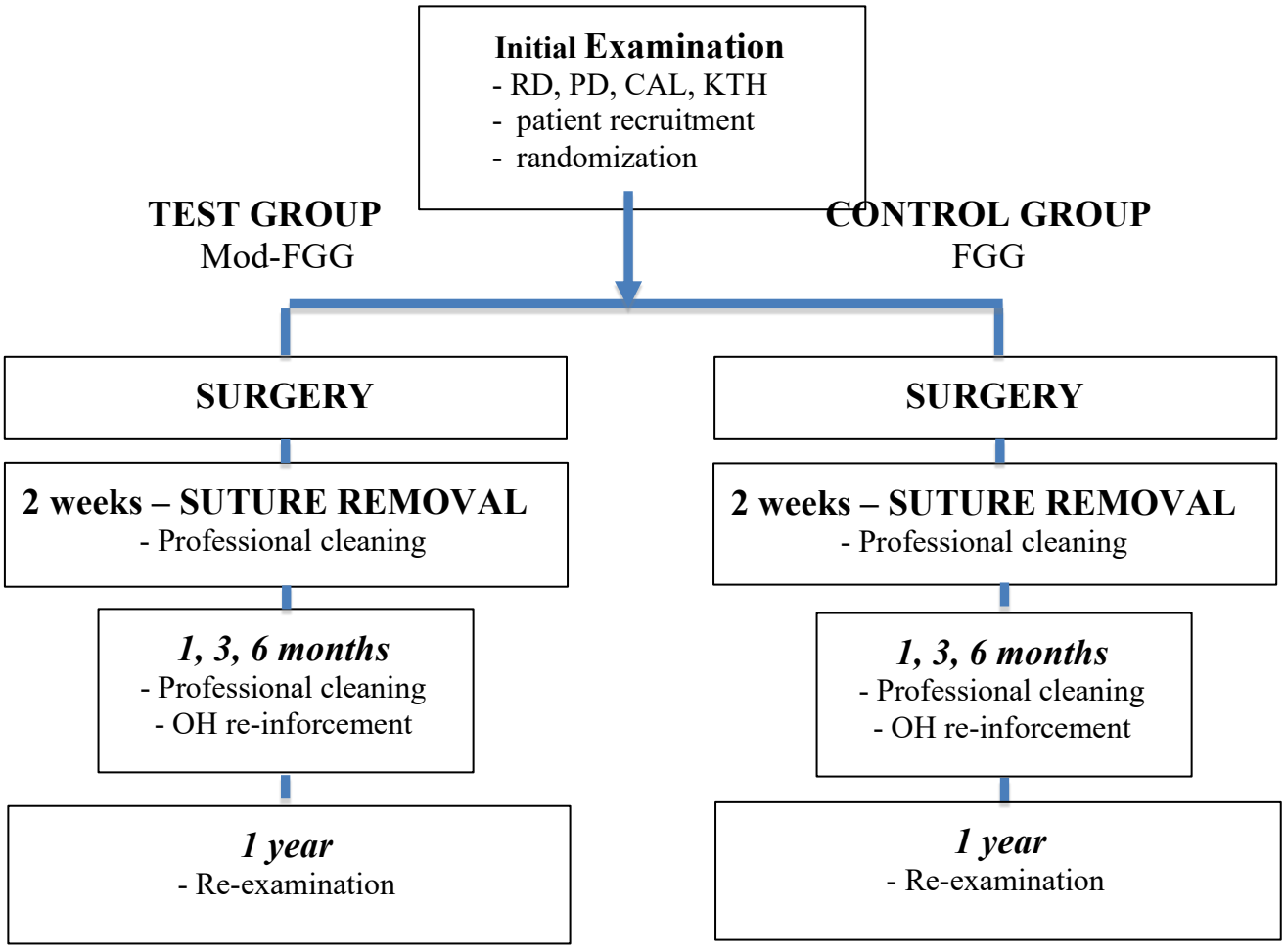
Sample size

The proposed sample size of 2x15 subjects has a power of 80% (alpha: 0.05; beta: 0.2) to detect a difference of the rate of CRC from 48% to 88% (22).

Ethical Requirements

The study protocol will be evaluated by the regional ethical board. All patients will be given information about the study design and their right to withdraw from the study at any time without negatively affecting their future treatment. Informed consent will be obtained from each patient willing to participate.

Study outline



References

1. American Academy of Periodontology. Consensus report on mucogingival therapy. Proceedings of the World Workshop in Periodontics. Ann Periodontol 1996: 1: 702–706.

2. Serino G, Wennström JL, Lindhe J, Eneroth L. The prevalence and distribution of gingival recession in subjects with a high standard of oral hygiene. J Clin Periodontol 1994: 21: 57–63.

3. Albandar JM, Kingman A. Gingival recession, gingival bleeding, and dental calculus in adults 30 years of age and older in the United States, 1988-1994. J Periodontol. 1999;70(1):30-43.

4. Cairo F, Nieri M, Pagliaro U (2014). Efficacy of periodontal plastic surgery procedures in the treatment of localized facial gingival recessions. A systematic review. 41 Suppl 15:S44–62

5. Graziani F, Gennai S, Roldán S, Discepoli N, Buti J, Madianos P, et al. (2014). Efficacy of periodontal plastic procedures in the treatment of multiple gingival recessions. 41 Suppl 15:S63–76

6. Huang LH, Neiva RE, Wang HL. Factors affecting the outcomes of coronally advanced flap root coverage procedure. J Periodontol. 2005;76:1729-1734

7. Aroca S, Barbieri A, Clementini M, Renouard F, de Sanctis M. Treatment of class III multiple gingival recessions: prognostic factors for achieving a complete root coverage. J Clin Periodontol. 2018;45:861-868.

8. Zucchelli G, Tavelli L, Barootchi S, Stefanini M, Rasperini G, Valles C, et al. (2019). The influence of tooth location on the outcomes of multiple adjacent gingival recessions treated with coronally advanced flap: A multicenter re-analysis study. J Periodontol 90:1244–1251.

9. Zucchelli G, Tavelli L, Ravida A, Stefanini M, Suarez- Lopez Del Amo F, Wang HL. Influence of tooth location on coronally advanced flap procedures for root coverage. J Periodontol. 2018;89(12):1428-1441.

10. Tonetti MS, Jepsen S, Working Group 2 of the European Workshop on Periodontology. Clinical efficacy of periodontal plastic surgery procedures: consensus report of Group 2 of the 10th European Workshop on Periodontology. J Clin Periodontol 2014: 41(Suppl 15): S36– S43.

11. Cairo F (2017). Periodontal plastic surgery of gingival recessions at single and multiple teeth. Periodontol 2000 75:296–316.

12. Wennström JL. Mucogingival therapy. Ann Periodontol 1996: 1: 671–701.

13. Zabalegui I, Sicilia A, Cambra J, Gil J, Sanz M. Treatment of multiple adjacent gingival recessions with the tunnel subepithelial connective tissue graft: a clinical report. Int J Periodontics Restorative Dent 1999: 19: 199–206.

14. Miller PD Jr. Root coverage with the free gingival graft. Factors associated with incomplete coverage. J Periodontol. 1987;58(10):674-681.

15. Bjorn H. Free transplantation of gingiva propria. Sven Tandlak Tidskr. 1963;22:684–689.

16. Nabers JM. Free gingival grafts. Periodontics. 1966;4(5):243-245.

17. Holbrook T, Ochsenbein C. Complete coverage of the denuded root surface with a one-stage gingival graft. Int J Periodontics Restorative Dent. 1983;3(3):8-27.

18. Cairo F, Nieri M, Cincinelli S, Mervelt J, Pagliaro U. The interproximal clinical attachment level to classify gingival recessions and predict root coverage outcomes: an explorative and reliability study. J Clin Periodontol. 2011;38(7):661-666.

19. Cortellini P, Bissada NF. Mucogingival conditions in the natural dentition: Narrative review, case definitions, and diagnostic considerations. *J Periodontol*. 2018;89 Suppl 1:S204-S213.

20. Jepsen S, Caton JG, Albandar JM, et al. Periodontal manifestations of systemic diseases and developmental and acquired conditions: Consensus report of workgroup 3 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. *J Clin Periodontol*. 2018;45 Suppl 20:S219-S229.

21. Carcuac O, Derks J. Modified free-gingival graft procedure for root coverage in the anterior mandible. *Accepted for publication in Int J Periodontics Restorative Dent.*

22. Zucchelli G, Marzadori M, Mounssif I, Mazzotti C, Stefanini M. Coronally advanced flap + connective tissue graft techniques for the treatment of deep gingival recession in the lower incisors. A controlled randomized clinical trial. *J Clin Periodontol.* 2014;41(8):806-813.