

Evaluation of the Treatment of Multiple Gingival Recession Using Modified Coronally Advanced Tunnel With Subepithelial Connective Tissue Graft Depending on the Positioning of the Graft

NCT06366022

04/10/2024

Current State of Knowledge

Thanks to the modified tunnel technique using an autogenous subepithelial connective tissue graft, we can effectively treat gingival recessions. [1] This surgical approach ensures minimal postoperative discomfort for patients, among other reasons due to minimizing vertical incisions and preserving the integrity of the interdental papilla. The material considered the gold standard in root coverage procedures is an autogenous connective tissue graft. [2] One method of harvesting it is de-epithelialization of a free gingival graft (FGG).

[1] Tavelli L, Barootchi S, Nguyen TVN, Tattan M, Ravidà A, Wang HL (2018) Efficacy of tunnel technique in the treatment of localized and multiple gingival recessions: a systematic review and meta-analysis. J Periodontol 89(9):1075–1090.

[2] Pietruska M, Skurska A, Podlewski Ł, Milewski R, Pietruski J (2019) Clinical evaluation of Miller I and II recessions treatment with the use of modified coronally advanced tunnel technique with either collagen matrix or subepithelial connective tissue graft: a randomized clinical study. J Clin Periodontol 46(1):86–95.

Purpose of the study

The aim of the present study is to compare the outcomes of a modified tunnel technique with an autogenous subepithelial connective tissue graft in gingival recessions, depending on whether the graft is positioned with its inner surface (previously adjacent to the periosteum) facing the covering flap versus its outer surface facing the covering flap.

Description of the study

- **Type of study:** randomized split-mouth interventional study.
- **Sample size:** 20 test sites and 20 control sites (20 patients)
 - a. **Inclusion criteria:**
 - I. Adult patients aged 18 to 60 years
 - II. Generally healthy patients or patients with controlled systemic diseases
 - III. Presence of multiple gingival recessions
 - b. **Exclusion criteria:**
 - I. Plaque index $\geq 20\%$ (Ainamo & Bay 1975)
 - II. Bleeding index $\geq 15\%$ (Mühlemann & Son 1971)
 - III. Tobacco smoking
 - IV. Uncontrolled systemic diseases with potential impact on tissue healing
 - V. Use of medications affecting healing (cytostatics, corticosteroids)
 - VI. Pregnant or breastfeeding women
- **Study endpoints:**
 - I. **Primary endpoint** – gingival recession/root coverage.
 - II. **Secondary endpoints** – gingival thickness, width of keratinized gingiva.

- **Procedure description:**

After obtaining written informed consent, the following periodontal parameters will be assessed: probing depth, height and width of gingival recession, gingival thickness (1 mm from the gingival margin), and width of keratinized gingiva. Then, under local anesthesia, root coverage surgery will be performed using a modified tunnel technique with an autogenous subepithelial connective tissue graft (sCTG). On the test side, the graft will be positioned with its inner surface (previously adjacent to the periosteum) facing the flap covering the graft, whereas on the control side the graft will be positioned with its outer surface facing the flap covering the graft. (Allocation of test and control sides will be determined by coin toss: heads = left side, tails = right side). After surgery, the patient will receive questionnaires assessing postoperative discomfort, separately for each operated side. Follow-up visits will be scheduled at 1 week and 2 weeks after the procedure. Measurements of the listed gingival parameters will be performed at 6 and 12 months postoperatively. Additionally, 12 months after surgery, a gingival biopsy (2.5 mm in diameter and 1 mm thick) will be collected for histological analysis.

Statistical analysis plan

The results will be presented using descriptive statistics such as means, standard deviations (SD), percentages, and frequencies. Baseline defect characteristics will be used to ensure test and control sides were similar. The analyzed metrics will be calculated as follows: (1) MRC = $\frac{GR_0 - GR_6}{GR_0} \times 100\%$ (after 6 months); MRC = $\frac{GR_0 - GR_{12}}{GR_0} \times 100\%$ (after 12 months), (2) recession reduction (GR red) = $GR_0 - GR_6$ (after 6 months); GR red = $GR_0 - GR_{12}$ (after 12 months), (3) CAL gain = $CAL_0 - CAL_6$ (after 6 months); CAL gain = $CAL_0 - CAL_{12}$ (after 12 months), (4) KTW gain = $KTW_6 - KTW_0$ (after 6 months); KTW gain = $KTW_{12} - KTW_0$ (after 12 months), and (5) GT gain = $GT_6 - GT_0$ (after 6 months); GT gain = $GT_{12} - GT_0$ (after 12 months). The normality of distribution of quantitative variables will be verified with the Shapiro–Wilk test. The primary outcome variable (MRC) will be tested for superiority by Student’s t-test. The secondary outcomes will be tested for side differences by Student’s t-test. If significant, the outcomes will be verified by repeated measures of variance, with subject as random effect used ANOVA approach. Pearson’s chi-squared test will be used for comparison of fractions and the agreement of variable class distribution between tests and controls. Statistical significance will be defined as p value < 0.05.

Benefits of the study

It is anticipated that the side on which the sCTG is positioned during the tunnel technique procedure will not affect the surgical outcome.

Risks of taking part in the study

Surgical treatment may cause pain, swelling, and bruising/hematomas of the gingiva and facial skin.