Efficacy of gingival retraction and hemostasis of Merocel strip compared with conventional retraction cord: a randomized controlled trial

MATERIALS AND METHODS

Study design and ethics

It was a randomized, double-blinded, split-mouth, active-controlled clinical trial. It occurred between May 2024 and July 2024 at the Department of Fixed Prosthodontics, Faculty of Dentistry, Damascus University. It was conducted per the Consolidated Standards of Reporting Trials (CONSORT) statement and Declaration of Helsinki, as revised in 2013. Ethical approval was provided by the Biomedical Research Ethics Committee of Damascus University (N1493). Signed written informed consent was obtained from each participant after explaining the treatment plan in detail.

Eligibility criteria

The inclusion criteria were as follows:

1. Healthy participants.
2. Participants older than 18 years.
3. Anterior teeth indicated for full coverage crowns.
4. The gingival sulcus depth is 1-2 mm.
5. The gingival biotype is thick.

The exclusion criteria were as follows:

1. Participants with systemic diseases that impact oral health, including cardiovascular and hematologic disorders, diabetes, and hyperthyroidism.
2. Pregnant participants.
3. Participants with periodontal diseases.
4. Participants are allergic to the materials used.
5. Abutments with abnormal size and position.

Out of 29 participants, 23 participants were included according to the eligibility criteria. The sample consisted of 122 abutments out of 134, including incisors, canines, and premolars in 23 participants, which was randomly divided into two groups:

- Group A: Gingival retraction was evaluated in 44 abutments of 8 participants.
- Group B: Hemostatic efficacy was assessed in 78 abutments of 15 patients.

Each group was further divided into two equal sub-groups using the split-mouth technique:

- Sub-group I (ACIKRC): Size 000 aluminum chloride-impregnated knitted retraction cord (SURE-CORD®, Sure-endo, Gyeonggi-do, South Korea) was applied.

- Sub-group II (MS): Merocel strips (Epistaxis Nasal Dressings, Eon Meditech, Gujarat, India) were applied.

Randomization and blinding

It was a double-blinded trial where participants and outcome assessors were masked to group allocation. Randomization was performed by applying a simple randomization method, which is flipping a coin.

Efficacy of gingival retraction

The finish line was initially prepared above the gingival margin and then placed 0.5 mm below the gingival margin. A conical bur with a non-cutting tip (Dentsply, Maillefer, Ballaigues, Switzerland) was utilized. The two-stage impression technique was considered utilizing condensation silicone (Zetaplus, Zhermack, Badia Polesine, Italy) before the gingival retraction. After achieving adequate isolation, retraction cords were applied using a single-cord technique. The final impression was taken utilizing condensation silicone in two stages. A virtual model of recorded impressions was created using a scanner (AutoScan-DS-EX Pro, SHINING 3D Tech Co., Ltd., Hong Kong, China). Virtual gypsum models were designed utilizing the exocad software (DentalCAD® 3.1 Rijeka, exocad, Hesse, Germany), and then a single gypsum model was created by matching models before and after gingival retraction (Fig. 1). A longitudinal section was determined of the prepared abutment from the incisal edge or the occlusal surface to the gingival margin parallel to the longitudinal axis (Fig. 2). The following measurements were considered at the following points for each abutment: midbuccal, mesiobuccal, distobuccal, midpalatal, mesiopalatal, and distopalatal. The angle of the gingival sulcus opening, which formed between the abutment surface and the inner surface of the gingival sulcus, was measured before and after gingival retraction (Fig. 3) by two blinded outcome assessors (ICC > 0.8). The difference between the two angles was calculated to determine the horizontal retraction.

Hemostatic efficacy

The finish line was initially prepared above the gingival margin and then placed 0.5 mm below the gingival margin utilizing a conical bur (Dentsply, Maillefer, Ballaigues, Switzerland). The bleeding was assessed before (t_0) and after (t_1) ginigival retraction according to Weir and Williams study by two blinded outcome assessors (ICC > 0.8) as follows:

Score 0 = No bleeding.

Score 1 = Bleeding controlled within one minute.

Score 2 = Bleeding not controlled within one minute.

After achieving adequate isolation, retraction cords were applied using a single-cord technique, and then the two-step impression technique was considered utilizing condensation silicone. In the first step, a heavy-body impression was made. The gingival retractor cords were removed after moistening the gingival sulcus with water to avoid damaging the sulcular epithelium, dislodging the blood clot, and causing bleeding. The hemostatic efficacy was evaluated according to Weir and Williams's abovementioned study. In the second step, a light-body impression was made.

Sample size calculation and data analysis

The sample size was calculated using the G*Power version 3.1.9.4 (Heinrich Hein Universität Düsseldorf, Germany). For group A, a sample size of 44 abutments achieved the following parameters: effect size of 0.86 (effect size d = 0.86), two-tailed 5% significance level (α = 0.05), 95% confidence interval, 80% statistical power (1-β err prob = 0.80), and 2 experimental sub-groups. For group B, a sample size of 78 abutments achieved the following parameters: effect size of 0.64 (effect size d = 0.64), two-tailed 5% significance level (α = 0.05), 95% confidence interval, 80% statistical power (1-β err prob = 0.80), and 2 experimental sub-groups. Data analysis was done utilizing IBM SPSS software version 24 (IBM SPSS Statistics® version 24, IBM Corp., New York, USA). Descriptive statistics of participants' characteristics were presented as frequency, percentage, mean, and standard deviation (SD). Descriptive statistics of gingival horizontal displacement angles and gingival bleeding scores were presented as mean, SD, standard error (SE), minimum (Min), and maximum (Max). The Kolmogorov–Smirnov test was applied to check the normality of data. An Independent sample t-test was conducted to compare gingival horizontal displacement angles and gingival bleeding scores between groups. A paired sample t-test was applied to compare gingival bleeding scores before and after retraction. The level of significance was adjusted at 0.05 ($p < 0.05$).