Effect of Professional Prophylaxis on Clinical Parameters and Patient Comfort: Randomized Clinical Trial

12/01/2022

Study Protocol:

After the initial evaluation of the participants and their inclusion in the study, the participants were randomized in blocks into group A where a conventional protocol was used in quadrants I and III and the test protocol in quadrants II and IV, and group B where a conventional protocol was used in quadrants II and IV and the test protocol in quadrants I and III.

The observations were made at three different times: baseline, one week after the intervention, and three weeks after the intervention. (Figure 1)

The clinical assessment of each participant was performed using the the Ainamo & Bay gingival bleeding index (GBI), the O'Leary plaque control record (PCR) and the Silness and Löe plaque index (PI). (26–28) The primary outcome variable of the study was the Gingival Bleeding Index (GBI) with the Plaque Index (PI) as a secondary outcome variable.

Hard and soft deposits were removed according to the protocol assigned in one appointment performed by the principal investigator the day after the first data collection. The control protocol consisted of mechanical scaling with Woodpecker® scaler (Guilin, Guangxi, 541004 P.R.China) at power 1, followed by stain removal and polishing with R&S RUBBER DOME (R&S® Dental products 25, Rue Bleue - 75009 Paris) with Prophy Paste CCS® polishing paste RDA 250 (Directa AB P.O. Box 723, SE-194 27 Upplands Väsby, Sweden) at a speed of 10,000 rotations per minute.

The test protocol consisted in an assessment of the periodontal status following the application of the plaque discloser (Biofilm Discloser, Dr. Wittmann GmbH & Co KG 64673 Zwingenberg - Germany), followed by oral hygiene instructions and biofilm removal with an erythritol jet (Airflow Plus Powder®, Electro Medical Systems S.A.), Chemin de la Vuarpillière, 31, 1260 Nyon - Switzerland) with the Airflow Prophylaxis

Master® device (Electro Medical Systems S.A., Chemin de la Vuarpillière, 31, 1260 Nyon - Switzerland). The jet stream was used at a power of 3 and the irrigation at a power of 10. Calculus removal was then performed with the piezon scaller of the same device using a PS scaler tip (Electro Medical Systems® S.A., Chemin de la Vuarpillière, 31, 1260 Nyon - Switzerland).

The first follow-up assessment (T1) was performed one week after the intervention, and the second follow-up assessment (T2) was performed 3 weeks after the intervention performed by the same research assistant that performed the initial assessment (T0). indecesThe precision and accuracy of the data collection was ensured by calibrating the instruments used and the investigators to minimize and control possible measurement errors. The assistant investigator underwent calibration before the start of the study to train the indeces, followed by a discussion of the criteria with the principal investigator.

After the appointment the participant rated comfort using a Visual Analog Scale measured on a Likert scale of 0 to 10 for each quadrant.

Statistical Analysis Plan:

The sample size was calculated for a power of 80% to allow the study to detect a difference at the 0.05 significance level when the true difference between treatments is 0.5 units.

Data were entered into SPSS® software (Statistical Package for the Social Sciences, IBM, Armonk, NY, USA), version 27.

Descriptive and inferential statistics were performed to evaluate the results of the two protocols, with a significance level of 5%. The mean values and standard deviations of the clinical parameters were calculated per protocol and per study group, and for the 3

evaluation moments: for the initial moment (T0), for the evaluation at 1 week (T1), and for the final evaluation (T2).

Comparisons between evaluation moments in each protocol were evaluated using the nonparametric Wilcoxon test for paired samples.

The Mann-Whitney U test was used to analyze differences between protocols. The Friedman test was used to analyze the differences between the different evaluation periods.