Evaluation of Dental Anxiety in Patients Undergoing Second Stage Surgery with Er,Cr:YSGG Laser Treatment: Randomized Clinical Trial

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Study **protocol**

This study was carried out on 96-healthy individuals, aged between 20-75 years, who underwent dental implant therapy in XXX University, Faculty of Dentistry, Departments of Oral and Maxillofacial Surgery and Periodontology and whose healing caps will be placed after second stage implant surgery. The findings of Eroğlu et al. were used to determine the sample size. According to this, it was calculated that 36 patients each should be included in the experimental and control groups in order to determine a 50% decrease in dental anxiety levels (β: 0.8, α:0.05). Considering the possible follow-up losses, it was decided that both groups consist of 48 patients. 96 patients were divided into two groups by randomization procedure (GraphPad Prism). The study was approved by XXX University, Faculty of Medicine, Ethics Committee of Clinical Research (XXX-01-24.11.2017). Authors declare that there was a preoperative information performed to all of the patients. All surgical procedures were carried out in accordance with the Helsinki Declaration. The osseointegrated implants embedded under the oral mucosa were exposed with a scalpel (Group 1) or Er,Cr:YSGG laser (Group 2). Totally-304 osseointegrated implants in 96 patients were evaluated clinically and radiographically in detail before the second stage surgical procedures. Patients without sufficient-keratinized gingiva at the implant shoulder region, those the tissue transposition techniques should be applied, those with high DAS score, implants that can not be localized due to gingiva thickness, implants with the possibility of bone overlap on closure screw and scalpel incisions greater tahn 1cm length (per implant) were excluded. For these reasons, 10 patients in Group 1 and 4 patients in Group 2 were excluded from the study. After all these evaluations, the second stage implant surgery was initiated with scalpel for 172 osseointegrated implants in 38 patients. The second stage implant surgery of 106 osseointegrated implants (Implant Direct, CA, USA) in 44 patients was performed with Er,Cr:YSGG (Figure 1).

All surgical procedures were performed by the same surgeon in both groups. In the scalpel group, second stage surgical procedures were carried out with standard technique. Local anesthesia was performed with 2ml of 40mg/ml articaine+ 0,012 mg/ml epinephrine (Maxicaine Fort, Vem İlaç San. ve Tic. Ltd. Şti, İstanbul, Türkiye) preoperatively. Incision was made on the area where the closure screw was reflected from the overlying mucosa and the closure screw was exposed. After insertion of the appropriate healing abutment, the procedure was completed by suturing if necessary. In the laser group, Er,Cr:YSGG laser (WaterLase iPlus; USA Biolase Technology Inc., Irvine, CA) with wavelength of 2780 nm was used on "implant recovery" setting suggested by the manufacturer and according to the recommended guidelines (pulse duration of 140–200 μs, repetition frequency of 100 Hz, H mode, output power of 2.75 W, and air/water proportion of 10/10%). MZ5 application tip was used in non-contact mode with target tissue to expose the closure screw and the appropriate healing abutment was placed.

Before the operation, all patients were informed about the method by which the implants would be exposed and informed consent was obtained from all participants. The patients were taken to the waiting room on the day of the second stage implant surgery and were asked to fill the STAI and DAS questionnaires for evaluating their anxiety levels. The STAI questionnaire was repeated in the control session (Post-op STAI) one week after the operation in order to verify whether the anxiety levels depend on the patient's general anxiety or due to the surgical procedure. In addition, demographic information such as age and gender, daily analgesic use after the operation and VAS scores during the operation and on the 1st, 2nd and 3rd days after the operation were recorded. Patients were

divided into four groups according to analgesic use. Surgical procedures and patient evaluations (preoperative and postoperative) were performed by different physicians due to single-blind study design.

Evaluation of Anxiety

STAI questionnaire, consisting of two parts with twenty questions each, was used to evaluate the level of state and trait anxiety in the participants (STAI-S: STAI State questionnaire and STAI-T: STAI Trait questionnaire). Both parts were evaluated separately. Patients' answers to each question were scored between 1-4 points. A total of 20-37 anxiety scores were assessed as minimum level of anxiety or none, 38-44 points as moderate and 45-80 as high.

In order to evaluate dental anxiety before treatment, DAS questionnaire consisting of 4 items including multiple choice answers was used. Patients' answers to questions were scored between 1-4 points. The total score of the questions in the questionnaire ranged from 4 to 20, and 4-11 points were interpreted as low level dental anxiety, 12-14 points as moderate and more than 14 points as high.

Statistical Analysis

In the evaluation of the demographic data Chi-squared test was used for the categorical variables to analyse the frequencies and ratios. For continuous variables, Student's t-test was used when normal distribution was provided and Mann-Withney U test was used when normal distribution was not provided. In the evaluation of DAS findings, anxiety levels in each group were examined by Chi-squared test. However, Mann-Whitney U test was used to determine the differences between the groups. VAS findings were analyzed by considering the generalized linear mixed model (GLMM) method based on Poisson distribution and AR (1) variance covariance matrix. Correlated p values obtained from the Holm-Tukey multiple comparison method were used for the comparisons of the least squares means in GLMM. In the GLMM model, the effects of the variables (group, time and analgesic consumption) on VAS values and their interactions were modeled. In the analysis of the findings of the STAI-S and STAI-T scales, the cross tabulations of the groups and anxiety categories were examined by the Chi-squared test. Mann-Whitney U test was used for comparisons between groups, and Wilcoxon test was used for intergroup comparisons. p values < 0.05 and 0.01 were accepted as statistically significant. All statistical analyzes used in the study were performed on the SAS 9.4 software. In the determination of the power of the statistical tests, the SAS software was used for VAS variables, and the G*Power software was used for the STAI S and T variables.