CLINICAL AND VOLUMETRIC EVALUATION OF COLLAGEN MATRIX EFFICACY IN ALVEOLAR SOCKET PRESERVATION. RANDOMIZED CLINICAL TRIAL

Study Protocol with Statistical Analysis Plan

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Scientific Background

Alveolar bone is a type of bone that is shaped by the development and presence of teeth, and which undergoes resorption after tooth loss, leading to a partial loss of its structural integrity (Monje et al. 2015). Horizontal and vertical resorption occurring in the alveolar bone after tooth loss leads to esthetic and functional problems, and also negatively affects the processes of prosthesis and implant placement (Pietrokovski et al. 1971). After extraction, various protection techniques have been developed in this process to optimize the healing of hard and soft tissues and minimize resorption (Vignoletti et al. 2012).

Guided tissue regeneration (GTR) is one of the most frequently used methods for preserving bone and soft tissues after tooth extraction (Vignoletti et al. 2012). This technique aims to support osteogenic cells by covering bone defect areas with barrier membranes and preventing the migration of epithelial cells (Pesce et al. 2022). However, it has limitations such as membrane exposure, risk of infection, and postoperative complications (Vignoletti et al. 2012).

The socket closure technique, as a less invasive alternative, involves closing the socket with autogenous or xenograft materials without raising a flap (Macbeth et al. 2022). It has been emphasized in the literature that this method optimizes the socket's healing process, and that collagen-based materials provide effective results in this area. The potential benefits of innovative materials like collagen matrices, such as reducing bone resorption and increasing keratinized tissue, are noteworthy (Macbeth et al. 2022).

Our research aims to evaluate the effect of a collagen matrix placed in the socket after tooth extraction on the changes in bone and soft tissue dimensions, based on these justifications.

Study design

This research was designed as a randomized controlled clinical trial and included 24 patients who presented to Altınbaş University Dental Hospital, were systemically healthy, and had extraction indications for their incisors, canines, and premolars. Patients who meet the study criteria will be informed about the research in writing and verbally, and individuals who wish to participate voluntarily will be asked to sign a "volunteer consent form." Informed consent forms for each patient will be stored in the patient file along with the patient measurement sheet.

Patients will be divided into two equal groups using a computerized randomization method. The tooth extraction will be performed under local anesthesia and without damaging the surrounding periodontal tissues. The extraction will be performed using periotomes, which atraumatically separate the tooth root from the periodontal ligament.

Control Group: The tooth extraction site will be left to heal spontaneously.

Test Group: The marginal gingiva around the abutment socket will be de-epithelialized using a rotary diamond bur. Subsequently, a collagen matrix (Mucograft Seal, Geistlich Pharma AG) will be selected and placed over the socket according to the appropriate socket diameter (8 or 12 mm). The spongier and more striated layer of the matrix will be positioned against the bone crest and secured to the de-epithelialized gingiva using a simple suture technique with 5/0 propylene sutures.

Imaging and Measurements In both groups, Cone Beam Computed Tomography (CBCT) will be performed on the same day after the procedure. The tomography will be performed with a slice interval of 1 mm and a slice width of 1.5 mm. During image analysis, axial and coronal reference points will be determined in the sagittal section: Axial reference point: Incisive foramen Coronal reference point: Midpalatal suture In the sagittal view, a line will be drawn along the long axis of the tooth, from the socket apex to the most coronal point. Lines perpendicular to the midline will be drawn from both the buccal and palatal regions of the cusp tip to measure the width of

the buccal and lingual cusps in millimeters. The length of the midline, from the socket apex to the crest tip, will be used to determine the height of the buccal and lingual crests. These reference points will allow for a comparison of the CT images taken on the day of the scan and on day 90 with minimal error.

Soft Tissue Assessment To evaluate soft tissue changes, measurements of keratinized gingival width and gingival thickness will be recorded initially and on the 90th day post-procedure.

Width of keratinized gingiva: Using a periodontal probe (UNC-15, Hu-Friedy), the distance from the mucogingival junction to the gingival margin on the mid-buccal surface of the relevant tooth will be measured.

Gingival thickness: It will be measured using a #25 endodontic spreader at the midpoint between the gingival margin and the mucogingival junction on the middle buccal surface of the tooth in question. Under local anesthesia (Ultracain, Sanofi), the spreader will be pressed vertically until it reaches the hard tissue, the silicone disk stopper will be slid until it contacts the gingiva, and the distance between the spreader tip and the inner border of the stopper will be measured with a digital caliper.

Follow-up Protocol Patients will be called for follow-up appointments on days 7, 14, 30 post-procedures, and at 3 months to assess the healing process and tissue integration of the collagen matrix. Intraoral photographs will be taken at all follow-up sessions to document the healing process.

Statistical Analysis Plan

The study will provide descriptive statistics for the data (number, percentage, mean, standard deviation, median, minimum, and maximum). The assumption of normal distribution will be checked with the Shapiro-Wilk test, and the assumption of variance homogeneity will be checked with the Levene test. In cases where the normality assumption is met, the Paired Samples T-test will be used to compare the two dependent groups, while the Wilcoxon Signed-Rank test will be used when the assumption is not met. In cases where the normality assumption is met, the Repeated Measures ANOVA test will be used to examine the difference between the means of three or more dependent groups; otherwise, the Friedman test will be applied. In cases where the assumption of normality is met, a Two-Way Repeated Measures ANOVA test will be performed for comparing three or more dependent groups and times. Post Hoc Bonferroni, Tamhane, and Adjusted Bonferroni tests will be performed to identify the group or groups that make the difference. When testing the relationship between categorical variables, Pearson's Chi-Square test will be applied if the sample size assumption is met, and Fisher's Exact test will be applied if the sample size assumption is not met. The analysis are planned to be performed in the IBM SPSS Statistics 27 program.