Treatment of Post-Extraction Dehisced Socket - A Case Series Study

NCT02980211

Updated on December 26th, 2019

Experimental Design and Center

This clinical study was designed as a prospective case series and it was conducted in compliance with the Preferred Reporting of Case Series in Surgery (PROCESS) guidelines.

Eligibility Criteria and Recruitment Adult subjects with tooth-bound, single-rooted teeth, except for mandibular incisors, that were indicated for extraction, and also presented with a large dehiscence defect affecting at least the coronal third of the buccal bone, were eligible to participate in the study. Exclusion criteria were as follows: 1) any periodontal attachment loss greater than 1 mm affecting the interproximal sites of neighboring teeth; 2) current heavy tobacco use, defined as greater than 10 cigarettes per day; 3) uncontrolled diabetes mellitus, defined as HbA1c>7.0; 4) severe hematologic disorders; 5) organ failure; 6) uncontrolled or severe metabolic bone diseases or disorders; 7) previous head and neck radiotherapy or chemotherapy within the past 12 months; 8) intake of medications known to largely influence bone metabolism; 9) subjects who were pregnant at the time of screening or trying to conceive; 10) mental disabilities that may interfere with reading, understanding and signing the informed consent and/or with following studyrelated instructions. Potential subjects were required to read, understand and sign the consent form. In the screening visit, candidates were informed of the purpose, design and timeline of the study, as well as expected benefits and possible risks associated with their participation.

Clinical Procedures All surgical procedures were performed by the first author (MA). Before starting the baseline surgical intervention, a cone beam computed tomographic (CBCT) scan (i-CAT Next Generation, Imaging Sciences International Inc., Hatfield, PA, USA) was made. The field of view was approximately 6 cm at 0.3mm voxel size and the exposure factor settings were fixed at 120 kVp and 5 mAs for all scans. All surgical procedures were performed under local anesthesia. The vertical extent of the defect was measured by determining the distance from the gingival margin to the crestal bone on the mid-buccal using a UNC-15 probe, and subtracting the 2 mm that, in average, would correspond to the supracrestal soft tissue. Tooth extraction was completed in a minimally traumatic, flapless, fashion. Following extraction, the existence of the suspected dehiscence defect was confirmed; absence of a defect resulted in subject exclusion. After carefully elevating one papilla, usually the distal, a soft tissue ‘pouch’ was created using tunneling instruments around the bony defect. Subsequently, a non-absorbable dPTFE membrane (Cytoplast TXT-200, Osteogenics Biomedical, Lubbock, TX, USA), trimmed to the size and shape that would allow for complete extension over the defect, was tucked between the mucosa and the alveolar bone. A combination particulate bone allograft composed of a mixture of 70% FDBA and 30% DFDBA (enCore, Osteogenics Biomedical Inc., Lubbock, TX) was used to fill the socket up to the crestal level and the surrounding buccal bone housing. The socket access was sealed with an extension of the dPTFE membrane to ensure compartmentalization of the underlying alveolar bone and grafting material. An external cross mattress and a simple interrupted suture (Cytoplast 5/0 suture, Osteogenics Biomedical Inc., Lubbock, TX) were applied to stabilize the marginal mucosa and the elevated papilla, respectively. Detailed post-operative instructions were given to the subjects, including care to avoid mechanical disturbance or excessive pressure of the surgical site and to avoid brushing the area for one week. Additionally, prescriptions were provided to each patient for an anti-inflammatory medication (Ibuprofen 600 mg, every 6 to 8 hours for 48 hours,

then as needed), a systemic antibiotic (Amoxicillin 500 mg every 8 hours for 7 days or, in case of penicillin allergy, Clindamycin 300 mg every 6 hours for 7 days) and a mouth rinse (Chlorhexidine gluconate 0.12% to be used every 12 hours). Subjects were recalled at 1, 2, 5 and 20 weeks to assess healing and level of discomfort. At 1 week, the sutures were removed. At 5 weeks, the dPTFE membrane was gently removed from ARP sites using a cotton forceps without administration of local anesthesia. At 20 weeks, a second CBCT was obtained for data analysis and to plan the implant placement procedure.

Outcome of Interest and Data Collection Alveolar Bone Volume Change Two independent examiners assessed the magnitude of volumetric reduction of the alveolar bone in mm 3 to express it as a percent of change from baseline to 20 weeks. The CBCT datasets (DICOM files) were imported into a software package (Simplant 17 Pro, Materialise, Dentsply Implants, Waltham, MA, USA). A constant threshold was used to separate the soft and hard tissue elements and manual segmentation using reproducible landmarks was performed to select a volume of interest (VOI) on both datasets. The VOI was confined to the following boundaries: a horizontal plane at the apical extent of the root tip or guiding landmark at the equivalent location when the tooth was not present (apical boundary), the alveolar crest (coronal boundary), the buccal and palatal plates of the alveolar bone (bucco-lingual boundaries), and vertical planes placed at the location of the interproximal height of contours of the adjacent crowns (mesio-distal boundaries). Volume of each VOI was computed automatically.

Statistical Analyses Given the nature of this study, no formal sample size calculation was conducted. A minimum sample size of 15 subjects was based on feasibility according to the low rate of large dehiscence defects reported in the existing literature. Data was uploaded to a statistical analysis software (SAS 9.4, IBM, Armonk, NY, USA). Normality was verified using the Shapiro-Wilk test. Measurements obtained by two examiners were averaged. Subsequently, mean and standard deviation was calculated for all variables. One sample t-tests were completed to determine whether the change in bone volume was significant (alpha was set to 0.05).