Acute Oroantral Communication Closure: Resorbable Collagen Membrane vs. Buccal Advancement Flap Outcomes: A Clinical Trial

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Study Protocol and Statistical Analysis Plan

Protocol Overview and Rationale

This investigator-initiated, prospective, non-randomized, parallel-group clinical study was designed to compare the clinical effectiveness and early radiographic healing associated with two surgical techniques for closure of acute oroantral communication (OAC) diagnosed within 24 hours after extraction of posterior maxillary teeth. The study was conducted at the Department of Dental Surgery, Faculty of Medical Sciences in Zabrze, Medical University of Silesia. The protocol was approved by the Institutional Review Board (PCN/0022/KB1/94/20/21), and all participants provided written informed consent prior to enrollment.

The study hypothesis was that minimally invasive closure using a resorbable heterogeneous collagen membrane would better preserve soft tissue architecture and reduce postoperative morbidity compared with the conventional Rehrmann buccal advancement flap, while maintaining comparable early bone healing.

Study Population and Enrollment

Consecutive adult patients presenting with acute OAC within 24 hours following extraction of a maxillary posterior tooth were screened for eligibility according to predefined inclusion and exclusion criteria. Twenty-four patients were enrolled; twenty completed the full 90-day follow-up and were included in the final analysis. The mean defect diameter was 3.5 ± 1.0 mm (range 2 to 5 mm), verified clinically and with limited-field CBCT on day 0.

Interventions and Standardization

Participants were assigned to one of two parallel treatment arms based on a predefined clinical protocol and the availability of the membrane technique at the time of treatment. Formal randomization and allocation concealment were not implemented.

All surgical procedures were performed by the same experienced oral surgeon to minimize operator-related variability. Preoperative preparation, socket debridement, smoothing of sharp bony margins, antibiotic prophylaxis, sinus precautions, analgesic recommendations, and follow-up schedules were standardized across both groups.

Experimental arm: closure using submucosal placement of a resorbable heterogeneous collagen membrane (Creos Xenoprotect) stabilized with horizontal mattress sutures following limited mucoperiosteal elevation without vertical releasing incisions.

Control arm: closure using the classical Rehrmann buccal advancement flap involving trapezoidal full-thickness mucoperiosteal flap elevation with vertical releasing incisions and periosteal releasing incision to permit tension-free coronal advancement.

Follow-up Schedule and Data Collection

Clinical assessments were conducted at baseline (day 0) and on postoperative days 1, 7, 14, and 90. The final radiographic assessment using limited-field CBCT was performed at baseline and at 90 days.

Clinical measurements (vestibular depth, keratinized gingiva width, alveolar socket dimensions) were performed using a calibrated WHO periodontal probe by an independent

examiner blinded to the surgical procedure. Examiner calibration was performed prior to study initiation using repeated measurements in a subset of patients.

Radiographic measurements and region-of-interest (ROI) density analyses were conducted by two trained investigators using standardized protocols in Romexis (v6.4) and ImageJ (v1.53k). Discrepancies were resolved by consensus.

Outcome Measures

Primary endpoint:

- Change in vestibular depth from baseline to 90 days.

Secondary endpoints:

- Change in keratinized gingiva width.
- Change in alveolar socket dimensions.
- Postoperative pain intensity measured with the Visual Analogue Scale (VAS) at days 1, 7, and 14.
- Incidence of postoperative complications (swelling, hematoma, epistaxis, wound dehiscence, persistent communication, fistula formation, clinical sinusitis).
- Normalized bone density at the surgical site derived from CBCT.

Radiographic Density Methodology
Because CBCT gray values are not directly equivalent to absolute Hounsfield Units, density measurements were normalized to adjacent cortical bone within the same scan to reduce inter-individual variability and acquisition-related bias. Regions of interest were placed at three standardized vertical levels of the alveolus (crestal, mid-alveolar, and apical). The arithmetic mean of normalized values was used for statistical analysis.

Statistical Analysis Plan

All analyses were performed using STATISTICA version 13.0. Continuous variables are presented as mean ± standard deviation. Categorical variables are presented as counts and proportions.

Assumption testing:

- Normality assessed with the Shapiro–Wilk test.
- Homogeneity of variance assessed with Levene's test.

Between-group comparisons:

- Independent-samples t test for normally distributed variables with equal variances.
- Mann–Whitney U test when parametric assumptions were violated.

Multiplicity control:
The primary endpoint retained a two-sided alpha of 0.05. Because multiple secondary endpoints were analyzed, Bonferroni correction was applied for secondary comparisons, and these results were interpreted as supportive.

Handling of missing data:
Only participants who completed the 90-day follow-up were included in the final per-protocol analysis. No imputation of missing values was performed.

Power considerations:
Given the final sample size (n = 20), the study was adequately sensitive for detecting large between-group differences in soft tissue outcomes but underpowered for moderate radiographic density effects. Therefore, CBCT density findings were prespecified as exploratory.

Bias Control Measures

- Single experienced surgeon to reduce procedural variability.
- Independent blinded clinical assessor.
- Dual-investigator radiographic analysis with consensus resolution.
- Standardized postoperative management in both arms.
- Objective probe-based measurements at predefined time points.

Safety Monitoring

Participants were monitored at each follow-up visit for adverse events, including infection, dehiscence, hematoma, epistaxis, persistent OAC, fistula formation, and signs of maxillary sinusitis. All complications were recorded prospectively. No serious adverse events related to the interventions were reported.

Ethical Considerations

The study complied with the Declaration of Helsinki and applicable institutional requirements. Participation was voluntary, and patients could withdraw at any time without affecting their treatment. Data confidentiality was maintained throughout the study.

Protocol Limitations

The protocol acknowledges limitations including non-randomized allocation, small sample size, short follow-up duration, and the known constraints of CBCT-derived density measurements. Findings related to bone regeneration are therefore considered hypothesis-generating and require confirmation in adequately powered randomized controlled trials with longer observation periods.

This Statistical Analysis Plan was finalized prior to database lock and outcome analysis.