- Official Title: CLINICAL, RADIOGRAPHIC, AND HISTOMORPHOMETRIC ANALYSIS OF ASTRA TECH IMPLANT EV PLACED AND IMMEDIATELY PROVISIONALIZED INTO PRESERVED ALVEOLAR RIDGES: A PROSPECTIVE 3-YEAR OUTCOMES STUDY
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Objective: The objective of this study is to compare and evaluate the stability of the implant body, survival rate, bone-level changes, and the implant's soft-tissue outcomes over a period of 1 year.

Design: This study is a cohort study (*ClinicalTrials.gov identifier- NCT04255342*)**.** The study population consists of adults aged 18-95 years old who are seeking care at the University of Iowa, College of Dentistry and Dental Clinics. Eligibility for the study included needing an implant placement and final crown delivery at the site of a single-rooted tooth that had previously undergone tooth extraction with bone grafting.

Methods: At least 3 months after tooth removal and bone grafting, consented subjects will undergo implant placement and immediate loading with a temporary crown. More specifically, a dental implant will be placed using Azento, a commercially-available product that uses computer technology to plan the dental implant placement using the AstraTech Implant System EV and an immediate implant temporary crown will be placed using Azento. After 3-months, a definitive all-ceramic crown will be placed that was made using a digital workflow. Participants will have a 1-year follow-up visit after placement of the definitive all-ceramic crown, specifically for data collection.

Statistical Analysis Plan: The volumetric and linear data obtained from the CBCT scans will be analyzed using the same test utilized for the histomorphometric data analyses, setting the significance level at 0.05. The Bonferroni method for correction will be applied and the false positive rate will be calculated. Wound Healing Index (WHI) values obtained will be analyzed using the Kruskal-Wallis test. The null hypothesis states that no differences in WHI will be found at different time points. Likewise, the self-reported level of discomfort and PROMs will be compared using the Kruskal-Wallis test. The level of discomfort and the post-op visits will be the dependent and independent variable respectively. The significance level will be set at 0.05. Other clinical variables recorded in this study will be presented using descriptive statistics (i.e., ITVs, marginal bone levels, and peri-implant mucosal outcomes). Nonetheless, the data will be assessed upon collection and suitability of appropriate analyses will be determined upon data distribution.

The specific variables that will be analyzed are as follows:
- Ability to place and provisionalize the implant following a completely digital protocol (e.g., Azento)
- Modified Wound Healing Scale
- PROM data on post-surgical discomfort
- Satisfaction with temporary crown and gum tissue
- Stability of implant during osseointegration healing phase
- Ability to use Azento digital file to fabricate definitive implant crown prosthesis
- Patient-reported outcome measures of satisfaction collected at 2-week, 6-week, Final Crown Delivery, 1-Year Visit)
- Clinical measure of peri-implant inflammation (probing depths, bleeding upon probing, keratinized gingiva, gingival index, plaque index)