- Official Title: Ultrasound-based Imaging to Detect Early Changes of Hard and Soft Tissue Around Immediately Placed Implants With or Without Soft Tissue Augmentation

- NCT Number: NCT05330702

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Objective: The objective of this study is to compare and evaluate the stability of the implant body's survival rate over a period of 6 months using three different methods of immediate implant placement along with either soft tissue grafting (Connective Tissue Graft, Volume-Stable Collagen Matrix) or no soft tissue grafting.

Design: This study is a randomized clinical trial (*ClinicalTrials.gov identifier - NCT05330702)*. 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 needed a tooth extraction and immediate implant placement at a location with the maxillary esthetic zone (first premolar to first premolar).

Methods: Immediately after tooth extraction, consented subjects underwent immediate implant placement and were randomized to either 2 groups of soft tissue grafting (connective tissue graft, volume-stable collagen matrix) or no soft tissue grafting. Participants have a 6-month follow-up visit after placement of the dental implant.

Statistical Analysis Plan: Values will be expressed as mean and standard deviation for continuous variables, such as linear measurements measured in mm, or absolute frequency and percentages for categorical variables. The normality will be assessed by means of a Kolmogorov-Smirnov test. The analysis of variance test or the Kruskal-Wallis's test with post-hoc analysis will be used to compare between three groups. Simple linear regression (univariate) analysis or analysis of covariance test will be employed to analyze the factors independently associated with peri-implant parameters. A two-tailed value of $P < 0.05$ is considered a significant level. Statistical analyses will be performed by the SPSS Statistical Software (IBM, version 28.0).