Linear and volumetric assessment of soft tissue augmentation with a Volume-Stable Collagen Matrix around immediate implants: A Randomized Clinical Trial

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BACKGROUND AND AIM

Immediate implant placement (IIP) is a reliable option for restoring hopeless teeth but may increase the risk of soft tissue complications. Volume-stable collagen matrices (VCMXs) offer an alternative to autogenous connective tissue grafts to increase soft tissue thickness. This randomized clinical trial compares linear and volumetric soft tissue changes around immediate implants placed with (test) or without (control) simultaneous soft tissue augmentation (STA) using a VCMX.

METHODS

- ✓ Patients requiring immediate implant placement in the anterior esthetic zone
- ✓ TEST group (STA with VCMX) and CONTROL group (NO STA)

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 4, 2021

ClinicalTrials.gov ID: NCT05081284

Study Identification

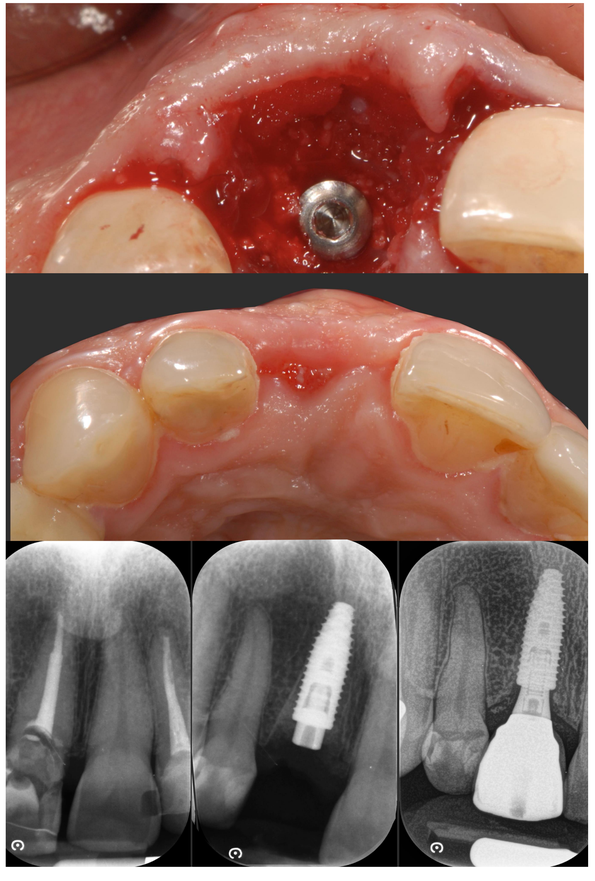
Unique Protocol ID:	19228
Brief Title:	Clinical Outcomes of Immediate Implants With or Without a Volume-stable Collagen Matrix
Official Title:	Clinical Outcomes of Immediate Implants With or Without a Volume-stable Collagen Matrix: a Randomized Controlled Clinical Trial
Secondary IDs:	

Ethical committee approval number: **19228 Comitato etico area vasta nord ovest, University of Pisa**

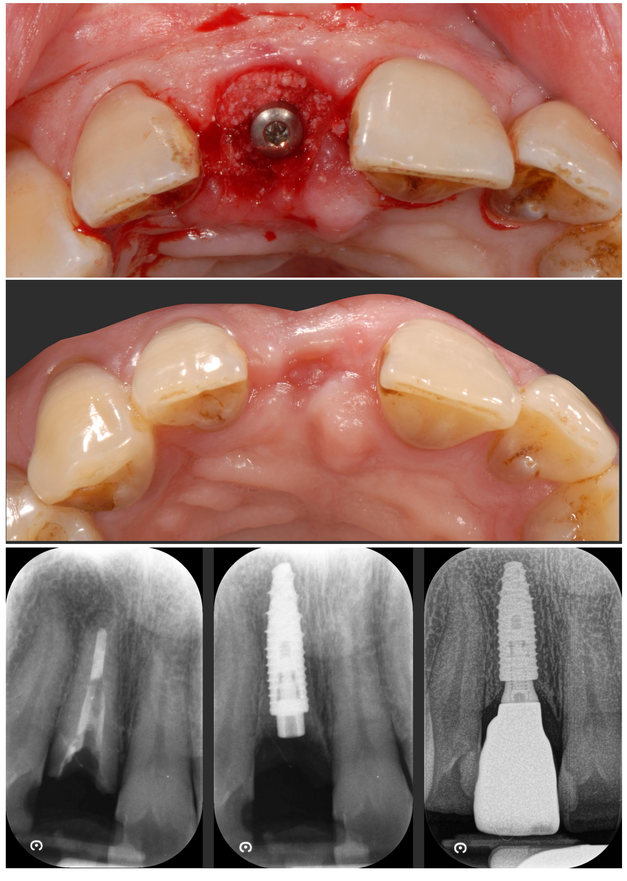
Clinicatrials.gov registration: **NCT05081284**

Operators briefing and examiners calibration

TEST



CONTROL



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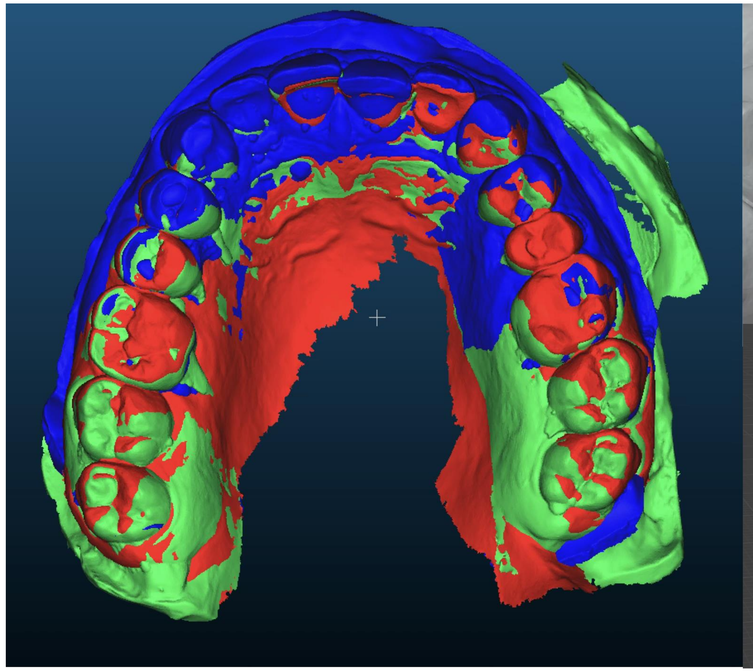
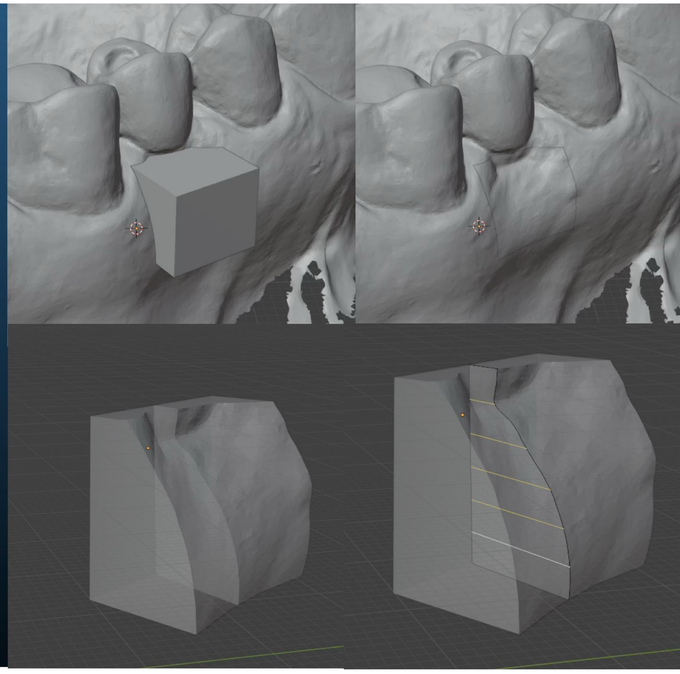
METHODS

- Linear and volumetric soft tissue changes were evaluated on digital intraoral scans obtained at baseline (T0), at six months (T1) and one year (T2), by using an optical scanner.
- Digital scans were aligned using reproducible reference points and processed.
- A standardized Region of Interest (ROI) was defined according to gingival and tooth landmarks. Within this ROI, linear changes measured at 1,2,3,4 and 5 mm from the gingival margin and volumetric changes were assessed along the tooth axis.





40 patients included → Available results for 22 → T0: no significant differences → Statistically difference at 3,4 and 5 mm from the gingival margin (Test Group)

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RESULTS

- Reduction in peri-implant soft tissue volume was observed in both groups between T0 and the subsequent time points, T1 and T2 ($p < 0.05$).
- At T1 and T2, the mean soft tissue volume was 178 ± 43 mm^3 and 168 ± 40 mm^3 in the test group, and 152 ± 65 mm^3 and 151 ± 67 mm^3 in the control group, respectively.
- The difference was not statistically significant at any time point ($p>0.05$); however, a trend in favor of the test group could be observed.