Dental Implant Stabilization with a Novel Bone Adhesive for Immediate Placement of Unstable Implants

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Joseph Fiorellini, DMD, DMSc[1], Alan Pollack DDS[2], George Kay DMD[2],Paul A. Fugazzotto, DDS PC[3]

[1] Department of Periodontics, School of Dental Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA,
[2] RevBio, Lowell, Massachusetts, USA
[3] Private Practice, Milton, Massachusetts, USA

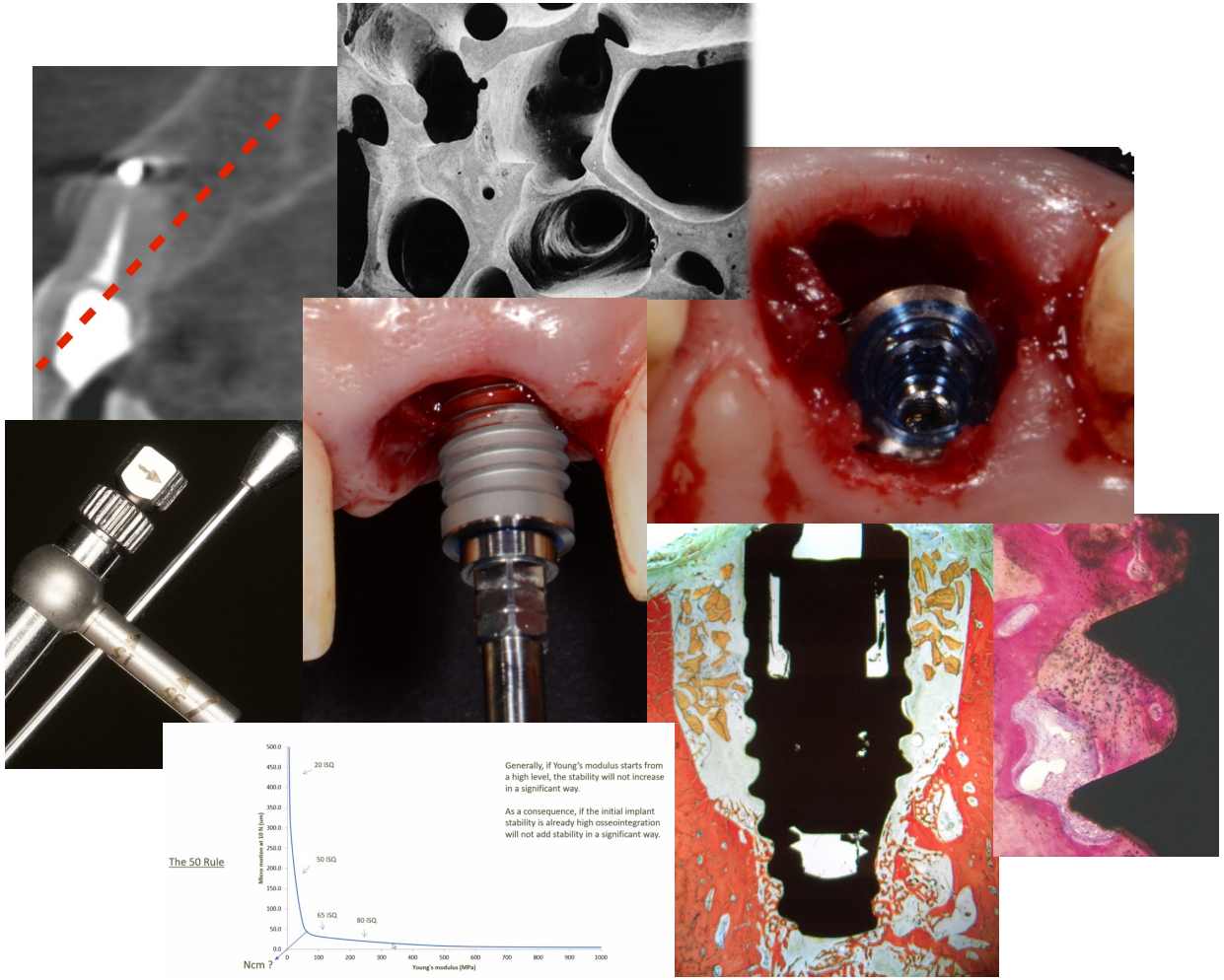
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Background

Dental implants have become the standard of care for many indications. Unfortunately, clinicians often encounter a lack of primary stability at the time of placement following tooth extraction. An adhesive composed of tetracalcium phosphate combined with phosphoserine (Tetranite® Implant Stabilization Material, TN-ISM) has been developed to provide implant stability at the time of tooth extraction and immediate implant insertion. Tetranite is a synthetic mineral-organic, osteoconductive matrix. TN-ISM is self-setting in a wet-field, cohesive and adhesive to metal and bone, and offers a simple solution to establish primary stability for unstable implants.

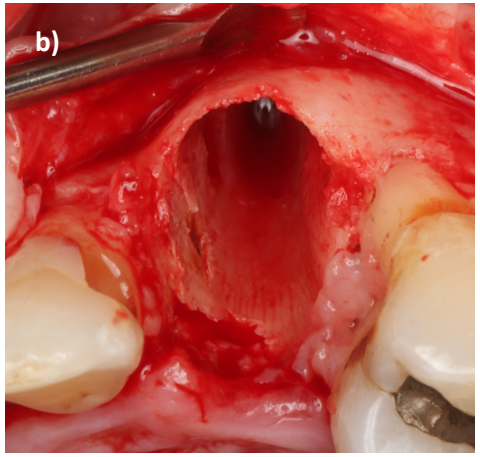
Aim

The aim of this clinical study is to evaluate dental implant survival following stabilization with TN-ISM following tooth extraction in patients.

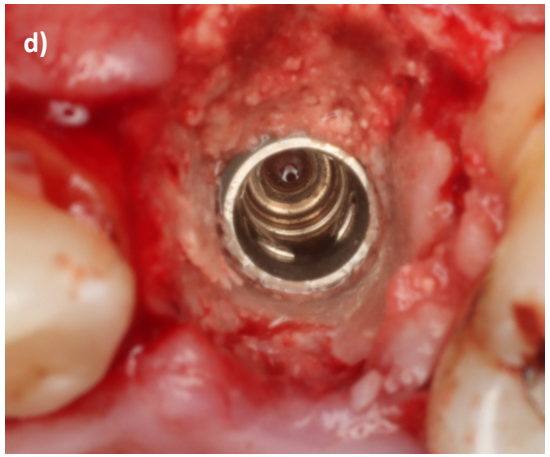


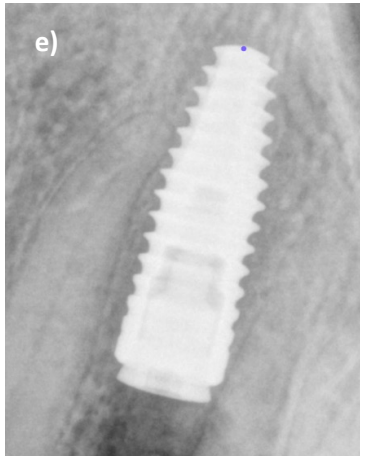
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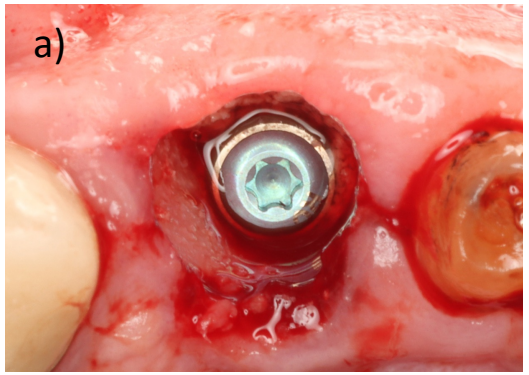
Materials & Methods

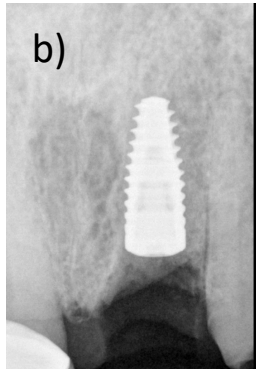
- A Human Studies Committee approved the study protocol.
- Inclusion criteria were immediate extraction socket, lack of primary stability (insertion torque <15Ncm, ISQ <60 in both directions and lateral mobility), at least 2mm of apical engagement for positive seating of implant.
- The clinical protocol included immediate extraction/implant placement with ISM stabilization as demonstrated by lack of implant mobility and ISQ >60 after 15 minutes curing of ISM.
- Implants were uncovered after thirteen weeks of healing.
- The primary evaluation parameters included dental implant success as defined by the modified Buser criteria, lack of implant mobility, ISQ >70 in at least one direction at 13 weeks post-placement, and no implant rotation with 35Ncm torque at 13 weeks post-placement.

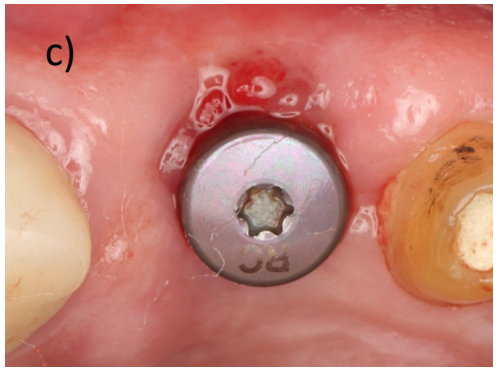
Figures (Case 1)

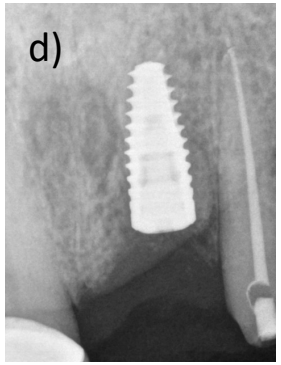
a) Unrestorable tooth prior to extraction
b) Extraction socket with apical implant osteotomy
c) TN-ISM Syringe
d) Implant placement with TN-ISM
e) Immediate post-insertion radiograph

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Results

A total of five patients were included in the preliminary phase of this study. There were 2 males and 3 females with a mean age of 60 years. 3 maxillary incisors, 1 maxillary canine and 1 mandibular molar were extracted and dental implants placed per the described protocol. Mean ISQ prior to ISM application was 7.8 and 69 after application. Healing was uneventful over the study observation period for all 5 patients. At the time of the second stage of surgery, implants were stable and satisfied the modified Buser criteria for success including resisting forward torque to 35Ncm for restorative records and crown preparation.

Conclusion

This study provides evidence that ISM-stabilized dental implants following immediate placement have a high rate of survival. Most importantly, the implants placed in the study would otherwise be contraindicated due to lack of stability without the use of the ISM. The placement of unstable implants with ISM has the potential to significantly impact patient care in terms of number of surgical procedures, time to restoration, cost, and patient satisfaction.

Figures (Case 2)

a) Implant/TN-ISM at placement
b) PA X-ray Immediate Post-op
c) Incisal View after Uncovering (13 wks)
d) PA X-ray at Uncovering (13 wks)

References:

1. Norton, M.R., et al., Bone glue - The final frontier for fracture repair and implantable device stabilization. International Journal of Adhesion and Adhesives, 2020. 102.
2. Cochran DL, Jones AA, Sugita R, Brown MC, Prasad H, Kay GW. Twelve-month evaluation of a novel mineral-organic adhesive material used to stabilize dental implants placed in oversized osteotomies in vivo in an animal model. Clin Oral Implants Res. 2022 Apr;33(4):391-404 .