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Osseodensification is a Novel Implant Osteotomy Preparation Technique That Increases Implant Primary Stability By Compaction and Auto-grafting Bone

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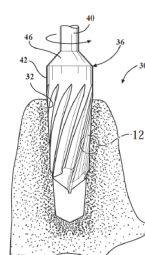
Introduction

- Bone-implant primary stability is crucial for osseointegration.
- There are many factors which can affect stability, including surgical technique and bone quality.
- The bone-implant interface is linked directly to the histological structure of bone and BMD.
- Maintaining sufficient bone bulk and density during the implant site preparation is essential to achieve necessary initial bone-implant contact and biomechanical stability.

Densah® Bur Technology



Densah® Bur is a new, multi-fluted osteotome design that can be used to prepare an implant site in bone by removing bone (analogous to a standard rotary bur), or through non-extraction bone preparation when rotating in the reversed, non-cutting direction.



- The objective of this study was to validate a novel non-extraction bone preparation technique that is highly controllable, fast and efficient, which we have termed "Osseodensification".

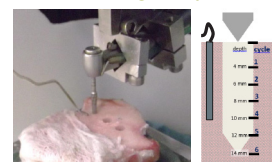
Hypothesis

- Osseodensification creates a densification layer by compaction and auto-grafting bone along the hole and this technique increases implant primary stability in cancellous bone compared with extraction drilling.**

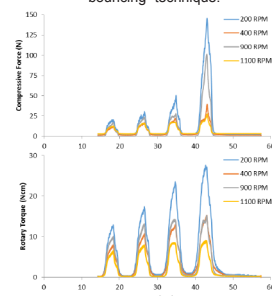
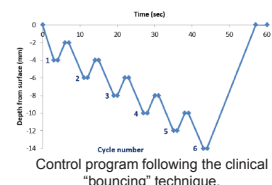
Methods

- 72 series of implant sites were prepared in 12 porcine tibial plateaus with the articular surfaces removed exposing cancellous bone.
- Precisely controlled bone preparation steps at 1.8, 2.8, 3.8, 4.8, 5.8 mm nominal Ø to enlarge the hole.
- A surgical drill (1100 RPM selected based on pilot data) with irrigation and a torque limiter (3i Implant Innovations) was mounted in a hydraulic testing machine.
- Preparation techniques
 - Standard Drilling (SD) with rotary bur
 - Extraction Drilling (ED) with Densah® Bur
 - Osseodensification (OD) with Densah® Bur rotating in the reversed, non-cutting direction.
- Measured insertion and removal torque of 4.1 & 6.0 mm Ø implants (n=8 each)
- Measured temperature increase during bone preparation.
- Implant stability (ISQ) was measured (Osstell).
- Morphology around holes was imaged with microscopy, SEM and quantified with µCT.

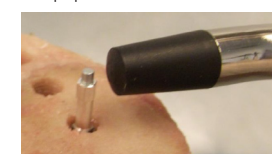
Testing Setup



Testing machine setup (Instron ElectroPlus E10000) with potted bone sample and drill motor installed in custom fixtures and thermocouple inserted.



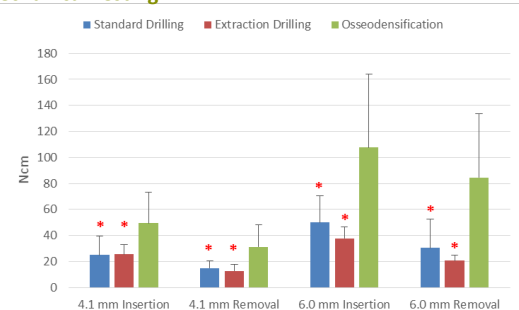
Pilot study results for axial force and rotary torque applied during the bone preparation at different RPMs.



Resonance frequency analysis of implant stability with Osstell system.

Results

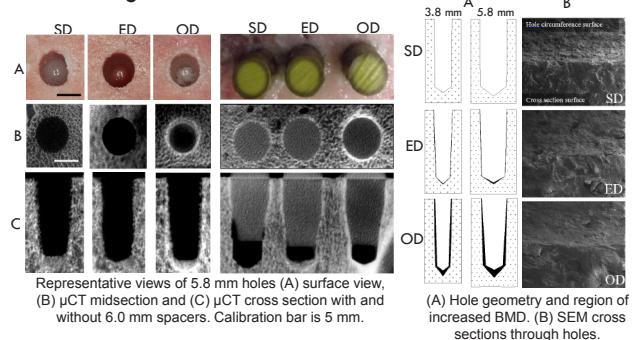
Mechanical Testing



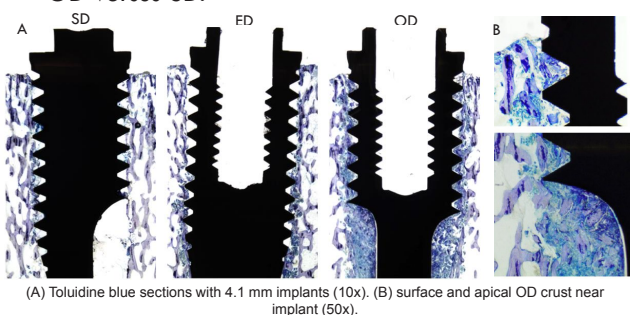
Measured maximum insertion and removal torques. * Significantly different than OD.

Results

- No difference in ISQ between groups.
- 3°C increase during drilling and 6°C for OD.
- OD Ø was 0.5 mm smaller than ED Ø.
- BMD increased around the periphery and bottom of OD holes.
- Bone particles auto-grafted into walls and bottom, creating smoother OD holes



Representative views of 5.8 mm holes (A) surface view, (B) µCT midsection and (C) µCT cross section with and without 6.0 mm spacers. Calibration bar is 5 mm.



(A) Toluidine blue sections with 4.1 mm implants (10x). (B) surface and apical OD crust near implant (50x).

Discussion

- Osseodensification has similar clinical safety to drilling when proper rotary speed, penetration speed and irrigation are used.
- Osseodensification creates a smaller hole than drilling due to recovery of elastic strain and creates a densification crust by compacting and auto-grafting bone along the entire depth of the hole.
- Osseodensification increases the bone-implant contact and primary stability.