Cancellous Bone Defect Healing with a Novel Bi-Phasic Calcium Sulfate – Hydroxyapatite Composite Injectable Bone Substitute

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Introduction

- A variety of synthetic bone void fillers are available with the most common based on calcium sulfate or calcium phosphate. Many of the calcium phosphate materials do not resorb or incorporate into the host skeleton quickly enough to be clinically satisfying.
- Conversely, many of the calcium sulfate-based products resorb too quickly to be adequately replaced by new host bone.
- The objective of this research was to evaluate Cerament, a novel injectable bone substitute cement with excellent radiocrescent properties.
- The hypotheses were that Cerament-filled defects would heal more quickly and completely than empty defects, producing more new bone formation.

Methods

- Institutional animal care and use committee approved protocol.
- Twelve six-month-old female New Zealand white rabbits.
- Cancellous drill-hole defects (8 mm by 5.0 mm dia), both lateral femoral condyles.
- Filled with Cerament or left empty.
- Bleeding drawn at 0, 2, 4, 24 hrs, 2, 3, 7 days, and 3, 7, 12 wks post-operatively and serum tested for iodine content.
- Calcein injection three days before sacrifice.
- Muscles were dissected free and perfused with saline solution.
- Calcaneal injection of formalin solution followed by a 5-10% solution of iohexol (USP 30).
- Iodine returned to baseline after one week.

Results

- μCT scanning (28 μm voxel size) was performed at three, seven, and twelve weeks.
- The μCT analysis (A) showed significantly more new bone formation within the filled defects compared to the empty defects at each time point (p<0.001).
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- Histologic analyses on femur samples after three (n=5) or twelve (n=7) weeks.
- Calcein labeling of undecalcified sections showed significantly more new bone formation activity within the Cerament filled defects compared to the empty defects (p<0.05).

Discussion

- Micro-CT imaging at three, seven, and twelve weeks showed minimal bone ingrowth or refilling in the empty defects.
- Bone formation was significantly greater at twelve weeks in the Cerament filled defects compared to empty defects (p<0.01).
- Histology showed the incorporation of the cement and the formation of significantly more new bone within the filled defects compared to empty defects (p<0.05).
- The amount of new bone and bone healing was evaluated and quantified using a 0-3 analog scale.
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References

5) Voor et al., ORS, 2010.