Preclinical Evaluation of Marrow Cellution Needle Compared to Traditional Aspiration and BioCUE Centrifugation System

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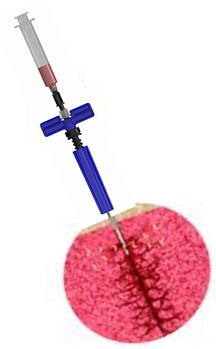
INTRODUCTION

- **Iliac crest bone graft (ICBG):**
  - Osteoinductive, osteoconductive and osteogeneic properties
  - Gold standard graft material for spinal fusion
  - Donor site morbidity
  - Limited graft volume
- **Bone marrow aspirate (BMA):**
  - Alternative source of osteogenic cells instead of ICBG
  - Less invasive with lower donor site morbidity than ICBG
  - Combination use with synthetic scaffolds and demineralized bone

Marrow Cellution BMA System (Ranfac, Inc.)	BioCUE BMA Concentration System (Zimmer Biomet, Inc.)
	
Specialized BMA needle that allows for harvest of high-quality stem and progenitor cells from various levels within the marrow space while limiting peripheral blood contamination.	System containing all components required to aspirate and process BMA.
No centrifugation required	Centrifugation required

OBJECTIVE: To compare the performance of the Marrow Cellution BMA needle system to the BioCUE BMA Concentration System in the ovine iliac crest.

HYPOTHESIS: The Marrow Cellution needle would result in higher TNCs and CFUs than traditional aspiration and the BioCUE BMA Concentration system.

METHODS

STUDY DESIGN:
- N=10 skeletally mature female sheep
- BMA collected from right and left iliac crests via fluoroscopic guidance under general anesthesia

MARROW CELLUTION BMA COLLECTION PROCESS:
- Marrow Cellution needle placed through dorsal cortex and into trabecular region of iliac crest to a depth of ~15-20mm
- Collection of ~1cc of BMA from three separate depths within the iliac crest for a total volume of 3cc

BIOCUE BMA SYSTEM COLLECTION PROCESS:
- ~25ml BMA harvested from single depth within contralateral iliac crest
- 3cc BMA set aside as a pre-centrifugation sample (i.e., traditional aspiration)
- Remaining BMA centrifuged and ~3cc of concentrated aspirate obtained

ASSESSMENTS:
- Total nucleated cells (TNC)/ml
- Colony forming units (CFU) count (small, medium, large, combined)
- CFU/ml
- CFU/TNC (ratio and %)

RESULTS

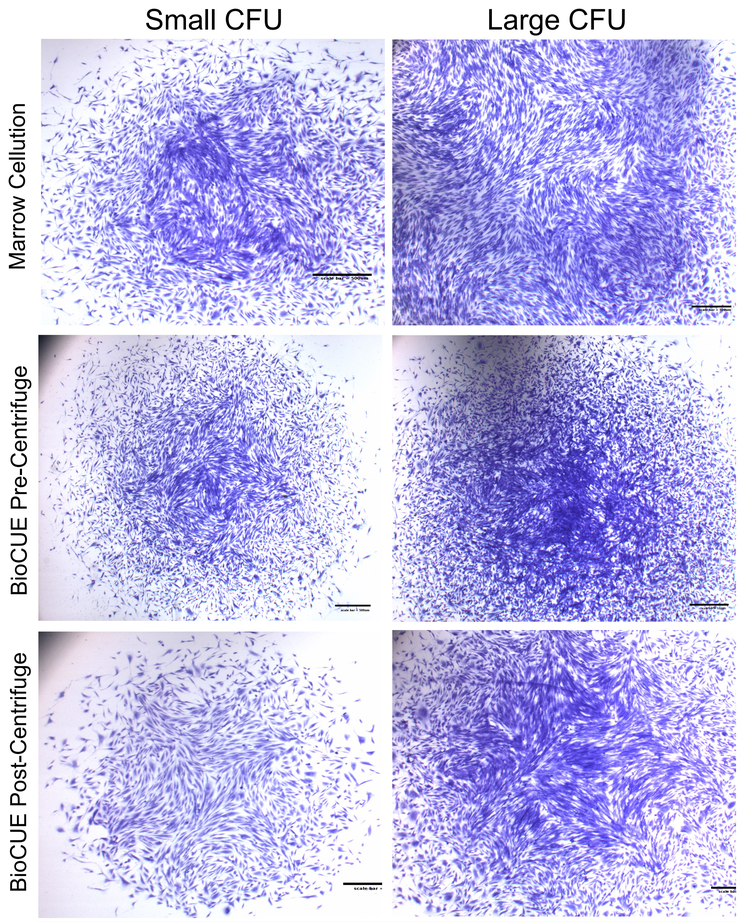


Figure 1: Representative images of colony sizes from a single animal showing Marrow Cellution, BioCUE Pre- and BioCUE Post-samples. Scale bar = 500 µm.

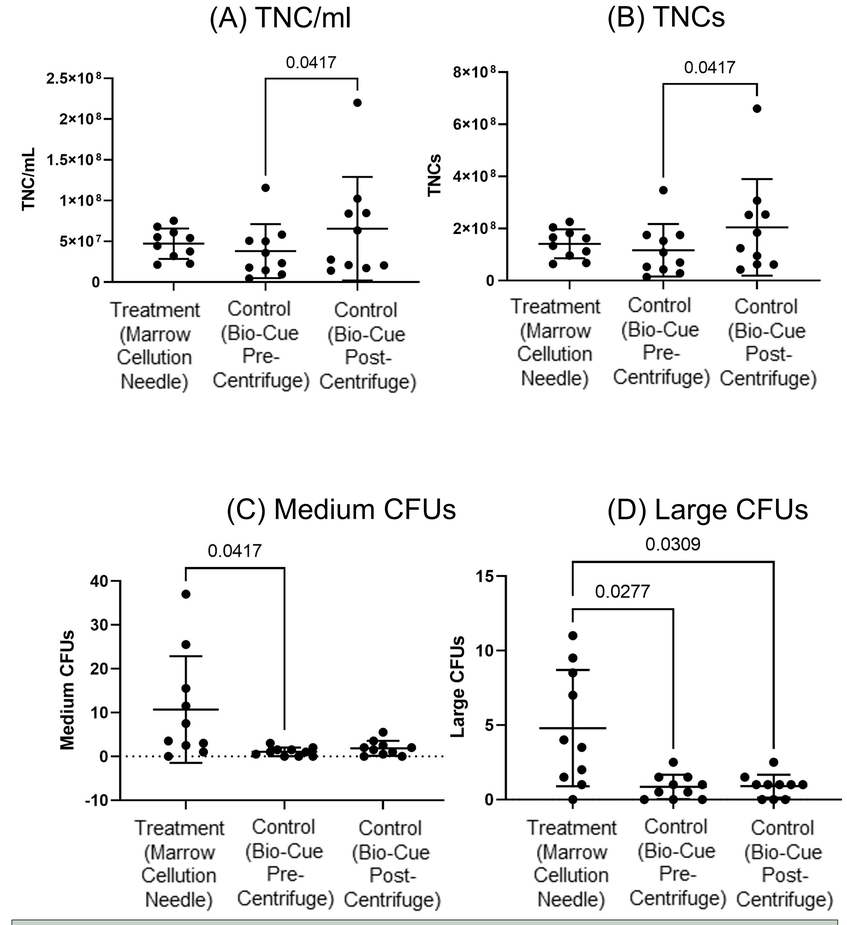


Figure 2: *Group comparisons* for A) TNC/mL, B) TNCs, C) Medium CFUs, E) Large CFUs. Data presented as Mean +/- STD with individual animals marked. Significant differences between groups denoted.

- No differences in TNC/ml or TNC parameters between Marrow Cellution and BioCUE Pre-centrifuge and BioCUE post-centrifuge
- Marrow Cellution medium CFUs were higher compared to BioCUE pre-centrifuge CFUs (p=0.0417)
- Marrow Cellution large CFUs were higher compared to BioCUE pre-centrifuge (p=0.0277) and BioCUE post-centrifuge CFUs (p=0.0309)
- No differences between any groups when CFUs were combined, however, a trend was noted in Marrow Cellution samples
- No statistical differences detected between any groups in CFU/TNC and CFU/TNC (%), however, a trend was noted in Marrow Cellution samples

DISCUSSION

- Marrow Cellution minimally manipulates cells, which may result in higher large CFUs compared to the BioCUE pos-centrifugation samples
- Most BMA concentration systems rely on a single site aspiration of large volumes of BMA followed by centrifugation resulting in
  - Increased peripheral blood contamination
  - Reduction of progenitor cell counts
- Marrow Cellution BMA System is a specialized needle that allows harvest of high-quality stem cell and progenitor cells from separate levels with the marrow space
  - Limits peripheral blood contamination
  - No centrifugation required

SIGNIFICANCE

- **CONCLUSON:** Marrow Cellution samples had approximately twice the CFU/ml and greater numbers of medium and large CFUs compared to BioCUE pre-centrifuge and post-centrifuge samples.
- Marrow Cellution BMA System may be an alternative system for improved bone marrow aspiration
- Future work should investigate the clinical impact of the Marrow Cellution BMA Needle System on functional outcomes in spine fusion procedures.

ACKNOWLEDGEMENTS

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