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

Jeremiah T. Easley[1], Katie J. Sikes[1], Katie Bisazza[1], Mindy Meyers,[1] Holly L. Stewart[1], Ben Reves[2]

[1]Department of Clinical Sciences, Colorado State University, Fort Collins, CO, [2]Medtronic, Inc., Memphis, TN
Jeremiah.easley@colostate.edu

Disclosures: Jeremiah Easley(N), Katie Sikes (N), Katie Bisazza (N), Holly Stewart (N), Ben Reves (3C – Medtronic)

INTRODUCTION: The "gold standard" for bone grafting in spinal fusion is iliac crest bone graft due to its osteoinductive, osteoconductive, and osteogenic properties. The retrieval of iliac crest bone graft can result in donor site morbidity and limited graft volume. Bone marrow aspiration (BMA) is an alternative source of osteogenic cells, specifically mesenchymal stem cells (MSCs), and is considered less-invasive with a lower harvest site morbidity compared to collection of autograft. Spinal fusion studies utilizing BMA in combination with synthetic scaffolds and demineralized bone matrices (DBMs) have been shown to result in high fusion rates. The use of BMA for hydration of graft material in orthopedic applications has become standard practice. The Marrow Cellution BMA System (Ranfac Corp.) is a specialized bone marrow aspiration needle that allows for harvest of high-quality stem and progenitor cells from various levels within the marrow space while limiting peripheral blood contamination and does not require centrifugation. The objective of this study was to compare the performance of the Marrow Cellution BMA needle system to the BioCUE BMA Concentration System (Zimmer Biomet) in the ovine iliac crest. We hypothesized that the Marrow Cellution needle would result in higher TNCs and CFUs than traditional aspiration and the BioCUE BMA Concentration system.

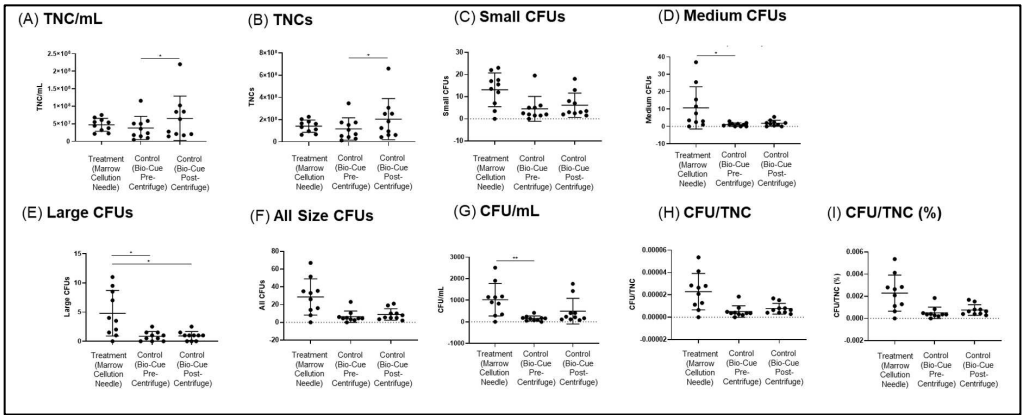
METHODS: The right and left iliac crests were utilized from ten (N=10) skeletally mature female sheep. All sheep were placed under general anesthesia in sternal recumbency and both iliac crest regions were clipped and sterilely prepped. Under fluoroscopic guidance, the Marrow Cellution needle was placed through the dorsal cortex and into the trabecular region of the iliac crest to a depth of approximately 15-20mm. The Marrow Cellution Instructions for Use (IFU) was followed to collect a total of approximately 3cc of BMA from three depths within the iliac crest. Similarly, the BioCUE kit IFU was followed to harvest approximately 25ml of BMA from a single depth within the contralateral iliac crest. An amount of 3cc was set aside as a BioCUE pre-centrifugation sample. (i.e. traditional aspiration). The remaining BMA was centrifuged, and approximately 3cc of concentrated aspirate was obtained. A total of 30 BMA samples (Marrow Cellution, BioCUE pre-centrifugation, and BioCUE post-centrifugation from 10 sheep) underwent analysis. Values for TNC/mL, CFU counts (small, medium, large, and all), CFU/mL, and CFU/TNC (ratio and %) were calculated. For non-parametric analysis, a pairwise Friedman test was performed, followed by Dunn's multiple comparisons tests to determine differences between groups in GraphPad Prism (v9.0.0; San Diego, CA). A P-value of < 0.05 was considered significant.

RESULTS SECTION: In regards to TNCs, no morphological abnormalities were noted for any samples. For group comparisons, the BioCue Pre-Centrifuge (i.e. Traditional aspirate) and BioCue Post-Centrifuge) groups demonstrated statistical differences in TNC/mL and TNC parameters. No differences in small CFU's were noted between groups, however medium and large size CFUs were significantly higher in the Marrow Cellution needle group relative to BioCue Pre and Post-centrifuge. When all size CFUs were taken together, no significant differences were noted, although trends suggest higher all size CFUs in the Marrow Cellution needle group relative to BioCue Pre-Centrifuge (p=0.1009) and BioCue Post-Centrifuge (p=0.3526) controls. These trends are being driven by the medium and large size CFU differences. No differences between groups were detected in the CFU/TNC and CFU/TNC (%) parameters; however trends were observed. Finally, a significant difference in the CFU/mL parameter was detected between the Marrow Cellution Needle and BioCue Pre-Centrifuge groups.

DISCUSSION: It is known that single site aspiration of large volumes of BMA result in increased amounts of peripheral blood contamination and a reduction in progenitor cell counts. Numerous commercially available BMA concentration systems rely on the initial aspiration of high volumes of BMA/peripheral blood prior to centrifugation/concentration. In contrast, the Marrow Cellution BMA System (Ranfac Corp.) is a specialized bone marrow aspiration needle that allows for harvest of high-quality stem and progenitor cells from various levels within the marrow space while limiting peripheral blood contamination and does not require centrifugation. Overall, these data suggest that bone marrow aspiration with the Marrow Cellution Needle results in higher levels of medium size CFUs relative to the BioCue System (Pre-Centrifuge) and large size CFU's relative to the BioCue System (Post-Centrifuge). Additionally, CFU/mL was increased with the Marrow Cellution Needle relative to the BioCue System (Pre-Centrifuge).

SIGNIFICANCE/CLINICAL RELEVANCE: This study successfully evaluated the performance of the Marrow Cellution BMA Needle System in comparison to traditional aspiration (Pre-centrifuge) and the BioCUE BMA Concentration System (post-centrifuge). With increased levels of medium and large-sized CFUs relative to BioCue Pre- and Post-centrifuge respectively, the Marrow Cellution BMA System may be an alternative system for improved bone marrow aspiration resulting in more MSCs with osteogenic potential. Future work should investigate the clinical impact of the Marrow Cellution BMA Needle System on functional outcomes spine fusion procedures.

IMAGES AND TABLES:



Group comparisons for A) TNC/mL, B) TNCs, C) Small CFUs, D) Medium CFUs, E) Large CFUs, F) All Size CFUs, G) CFU/mL, H) CFU/TNC (ratio), and I) CFU/TNC (%). Data presented as Mean +/- STD with individual animals marked. Significant differences between groups denoted (*p<0.05, **p<0.01).