Bone Marrow Concentration vs. Iliac Crest Bone Graft: 2-Year Results in a Single-Blinded Randomized Controlled Trial on Thoracolumbar Spinal Fusion Bone Grafts in Multi-Level Adult Spinal Deformity

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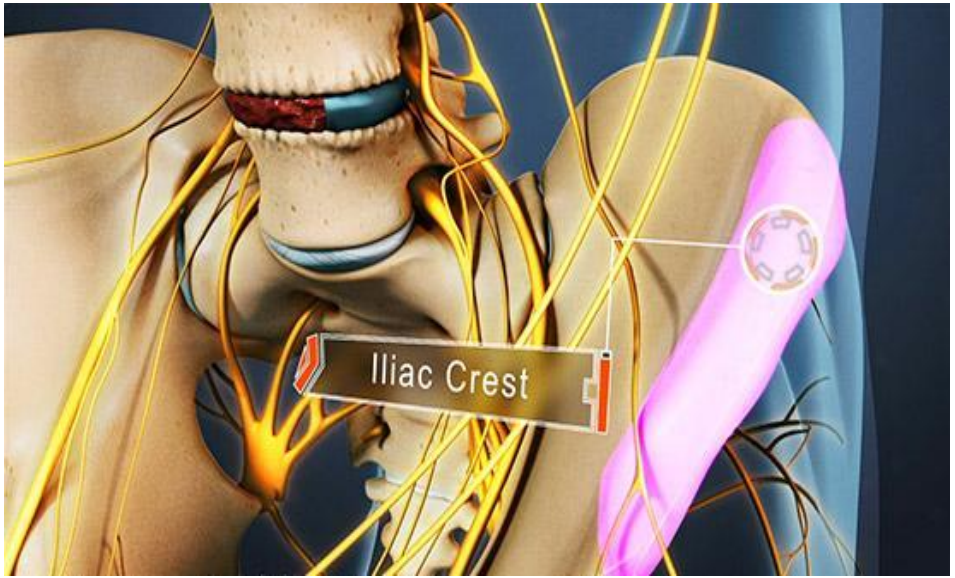
Background

- Biologic therapies enhance spinal fusion, prevent nonunion and complications which may result in significant pain and disability.[1,2,3]

- The “gold standard” is autologous bone graft obtained from the iliac crest (**ICBG**)[4,5]
  - Pros: osteoconductive scaffold, osteogenic factors, and cellular elements that promote arthrodesis.
  - Cons: limited supply, significant donor site pain, postoperative morbidity

- Alternative techniques to enhance spinal fusion have been studied, resulting in the development of bone marrow concentrate (**BMC**).[6]



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Study Objective

- Previous literature has found **BMC** to display comparable angiogenic, osteoinductive, osteoconductive, and osteogenic properties as **ICBG**.7
- Several recent studies have proposed utilizing **BMC** combined with allograft cancellous bone chips (**BMC+Allograft**).[8–10]
- The major advantage of **BMC+Allograft** is the ability to obtain a greater volume of osteogenic bone precursor cells without the morbidity of iliac crest harvest (**ICBG**).
- **BMC+allograft** has been shown to improve fusion rates compared to allograft alone, and has equivalent fusion rates compared to **ICBG**,[8,10] the only in vivo study performed was reported on **1 to 3 level fusions**.

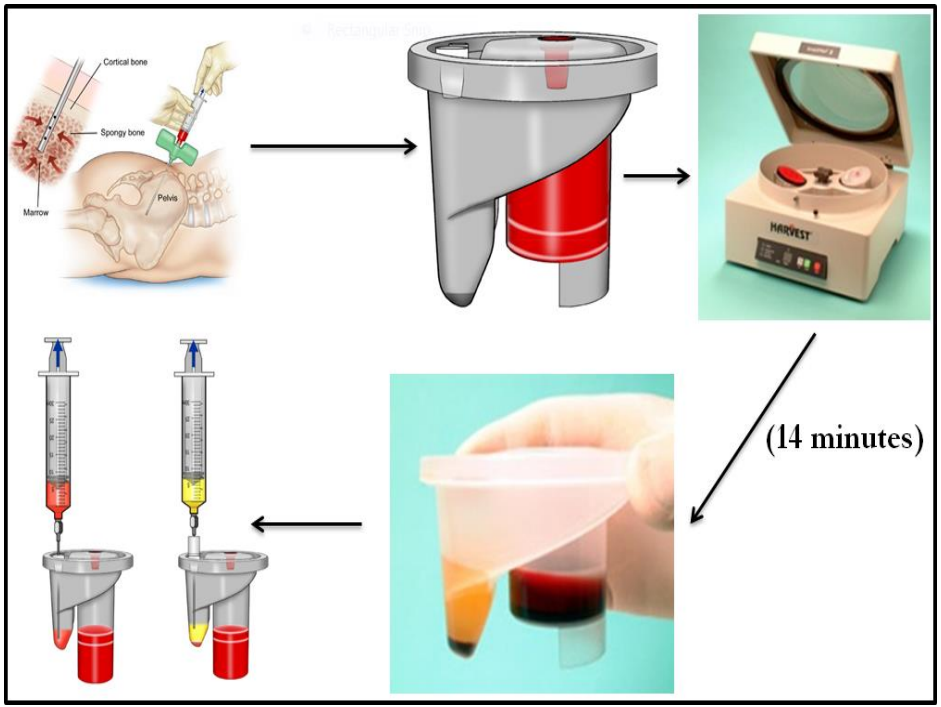
- **Our goal was to examine the differences between BMC+Allograft and ICBG during posterior lumbar or lumbosacral multi-level spinal fusions.**

Materials & Methods

- Design
  - Prospective single center randomized clinical trial.
- Inclusion Criteria:
  - Age >18 years w Adult Spinal Deformity, Failed at least 6 weeks of conservative care with
  - Posterior spinal fusion: Thoracolumbar spine or lumbar spine
  - Oswestry Disability Index (ODI) score >30%
- Exclusion criteria:
  - Spondylolisthesis grade ≥3, Metabolic bone disease, Use of medications that may interfere with bone healing. Active malignancy
- Patient Groupings
  - Randomized in a 2:1 ratio:
    - BMC+allograft
    - ICBG
- Collected data:
  - Demographics, medical comorbidities, surgical details, and treatment complications
  - Baseline to 2-Years postop
  - HRQL: ODI, Short Form 12 (SF-12), Numeric Pain Rating Scale (NRS-Pain)
  - Aspirate data of both **BMC** and **ICBG** groups (assessed by an independent laboratory).
    - Total nucleated cell concentration
    - Platelet Concentration

Materials & Methods

- Intervention Technique
  - All patients received **open posterior lumbar fusion. ≥4 level fusions** with sacrum extensions also **received interbody fusions** at L5-S1 and **bilateral iliac fixation**.
- (**BMC+Allograft Harvesting**)
  - Bone marrow aspirate (**BMA**) was aspirated from the posterior iliac crests.
  - **BMA** was pooled with anticoagulant citrate dextrose solution, concentrated via centrifuge (**BMC**), and then packed with cancellous bone chips yielding 10 mL bone logs (**BMC+Allograft**).



Materials & Methods

- Fusion Assessment
  - Performed by two independent radiologists.
  - Fusion status was classified according to Tan et al:
    1. Complete Fusion
    2. Partial Fusion
    3. Unipolar Pseudarthrosis
    4. Bipolar Pseudarthrosis

- Statistical Analysis
  - **Frequencies:** assessed Demographics
  - **Non-parametric Mann Whitney U and Wilcoxon Signe-Rank tests:** compared complications, fusion grading, biologic quality, HRQLs within and between groups.
  - Level of Significance was set to P = 0.05

Results

- **27** Patients included
  - **17 BMC+Allograft**
  - **10 ICBG**
- Demographics [Overall Cohort]
  - Mean age **56** years old (range: 35-77)
  - **60%** Female
  - **44%** Unemployed
  - **48%** Smokers
  - **40.7%** History of Spinal Surgery
  - **No significant differences between BMC+Allograft and ICBG** (**all p>0.05**)

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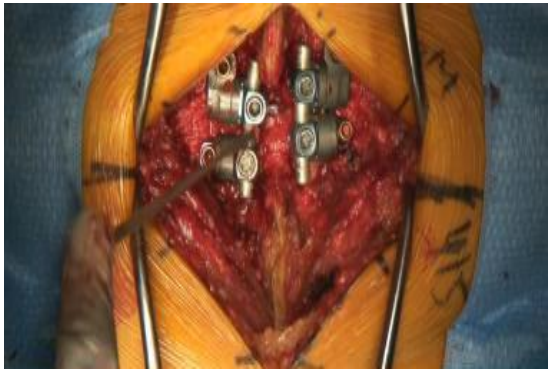

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Results

- Complications
  - **No significant differences in overall complications** (**p=0.935**), **reoperations** (**p=0.201**).
  - **ICBG** patients had significantly greater **incidence of rod breakage** (**p=0.024**)
  - No significant intraoperative complications related to BMC+Allograft or ICBG protocol.
  - Complication Details: within the 2-year follow-up period
    - BMC+Allograft
      - **7** complications (**41.1%**)
      - **3** re-operations (**17.6%**)
        - 1 non-union, 1 persistent radiculopathy, 1 hardware removal.
    - ICBG
      - **4** complications (**40%**)
      - **4** re-operations (**40%**)
        - **3** hardware failure (two rod breakage), 1 patient fall.

Results

Surgical Details: All clinical values for interventions were similar due to cohort randomization (All P>0.05).

BMC+Allograft

- Avg. levels fused: 6.0
- Estimated Blood Loss (EBL): 2542 ±1425
- Avg. OR time: 7:26 ±2:20

Techniques (Prevalence)

- Osteotomy: 62.5% ±51.8%
- 3-Column Osteotomy:11.7% ±33.2%
- Decompression: 85.7% ±37.8%

ICBG

- Avg. levels fused: 6.2
- Estimated Blood Loss (EBL): 2102.9 ±1201
- Avg. OR time: 8:15 ±2:49

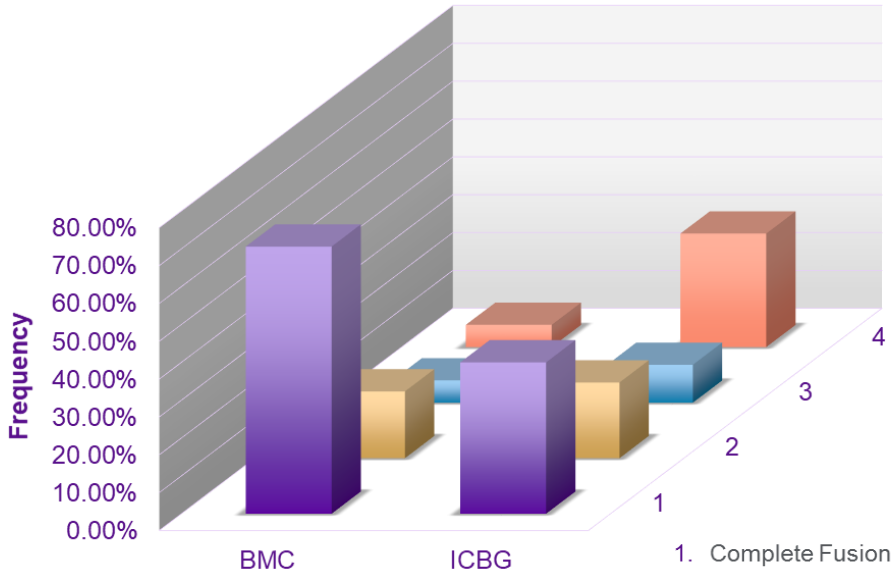
Techniques (Prevalence)

- Osteotomy: 70.6% ±47.0%
- 3-Column Osteotomy: 20% ±42.2%
- Decompression: 86.7% ±35.2%

Results

- Post-Operative Fusion Evaluation
  - 88.2% of BMC patients were graded ‘fused’ at 1-year follow-up, and 60% of ICBG patients (**p=0.088**)
  - Based on the described Lenke 1-4 classification, **BMC patients trended towards better fusion scores, but insignificantly (BMC average: 1.5 vs. ICBG average: 2.3, p=0.062**).
- Effect of Smoking Status on Arthrodesis
  - 61.5% of patients with a history of smoking were graded ‘fused’ at 1-year follow-up, and 92.9% of non-smoking patients were graded ‘fused’ (**p=0.05**).

BMC+Allograft vs. ICBG Fusion Grade Frequencies



1. Complete Fusion
2. Partial Fusion
3. Unipolar Pseudarthrosis
4. Bipolar Pseudarthrosis

Results

- Aspirate Analysis - Biologic Quality
  - **No significant associations were observed between number of nucleated cells, number of platelets, reaching threshold of >1500 BMC cells x10^6 per cm3 (Threshold proposed by Herigou et al), and improved fusion scores (all P>0.05).**
- 2-Year Outcome **HRQLs**:
  - **Both Patient groups improved from baseline to 2-Year postop**
  - **No significant differences were observed between either group in baseline, changes to, or 2-year followup HRQLs (ODI, NRS Back, SF-12 MCS, SF-12 PCS) (p>0.05).**

Conclusions

- Limitations:
  - Small patient population (n:27)
  - No ICBG data for nucleated cell and platelet count
  - Fusion score was assessed by the lowest score of any vertebra in the construct (not combined or individual levels).

- BMC+Allograft
  - Associated with less hardware failures
  - Trended towards better fusion scores
  - **A viable alternative, with similar HRQL outcomes and overall complication rates compared to ICBG.**

Thank You!

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