# Allograft Reconstructed IBG Donor Site Remodels to Viable Bone and its Preliminary Clinical Effectiveness in Revision Fusion

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#### Disclosure

Glenn R. Buttermann, MD
Research and development agreement with
FG Solco for a lumbar plate

Andrew L. Freeman, M.S. Byron H. Simmons, M.D. No conflicts



#### Introduction

- Bone autograft options may be limited in revision spinal fusion cases if prior IBG harvested or iliac fixaton.
- BMP expensive, not allowed (off-label), or not covered by payors.
- Other bone substitutes are not reliable for revisions.
- Reconstruction of the iliac bonegraft donor site may allow for re-harvest for patients who subsequently have a secondary fusion.



### Study Purpose

 Assess the *viability* of bone graft donor sites after reconstruction with freeze-dried cancellous bone allograft.

 Ascertain whether the reconstructed iliac bone graft, RIBG, sites could be re-harvested for obtaining a successful arthrodesis in patients who had a secondary fusion.



# Methods – Prospective Study

- Lead author routinely reconstructed IBG donor site, with freeze-dried allograft chips, to reduce pain.
- Study group: Consecutive patients who had their IBG donor site backfilled, *RIBG*, and subsequently had secondary fusion surgery for a *pseudarthrosis* repair or fusion extension.
- Time to secondary surgery was 2.3 yrs in pseudarthrosis repair, & 8.2 yrs in fusion extension groups.
- Lumbar CT prior to secondary surgery included RIBG site.



## Methods – Prospective Study

- RIBG biopsies obtained at the time of secondary fusion. Histology analyzed the ratio of filled to unfilled lacunae of osteocytes & cellularity of marrow.
- Histology control group: Patients who had normal iliac bone Bx.
- One year postop CT scans after secondary surgery to assess revision fusion rate. Controls consisted of revision fusion with iliac bone graft (IBG) or bone morphogenic protein (BMP).
- VAS & ODI evaluated the clinical success of the secondary fusion surgery using RIBG.



## 2 Patient Groups (total n = 16)

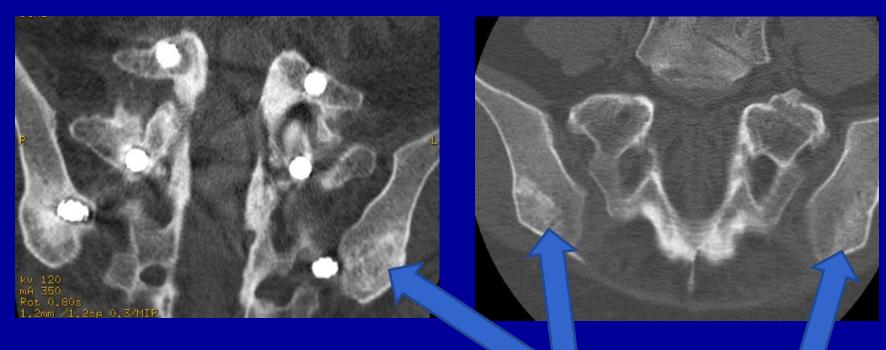
	Pseudarthrosis Repair PSF extension		
	n=7	n=9	Total
Age, years, mean ± SD	53.7 ± 12.8	56.3 ± 3.8	55.1 ± 8.9
#levels fused, mean	1.7	2.0	1.9
Period to secondary			
surgery, years, mean ± SD	2.3 ± 1.1	$8.2 \pm 3.3$	-
Fusion supplement			
BMP*	3 (43%)	3 (33%)	6 (38%)
Internal BGS	1 (14%)	1 (11%)	2 (13%)
Both BMP & BGS	3 (43%)	1 (11%)	4 (25%)
None	0 (0%)	4 (44%)	4 (25%)

Fusion supplements = Limitation/confounding factors

BGS = bone growth stimulator



# CT scan of RIBG site Prior to Revision Fusion



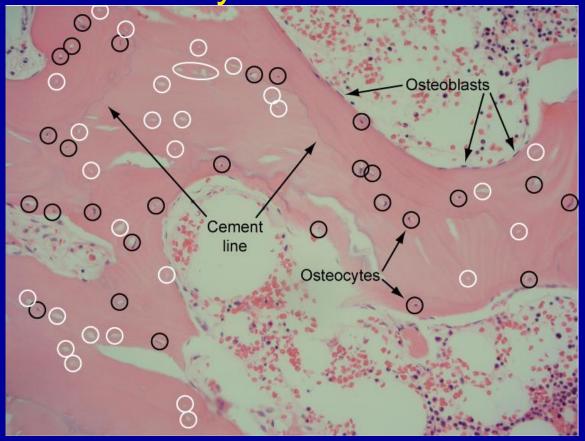
Cortico-cancellous 9/16 patients

Cancellous 7/16 patients



# RIBG Histology Results

(% viable osteocytes = filled/total lacunae)



Black = filled lacunae White = empty lacunae

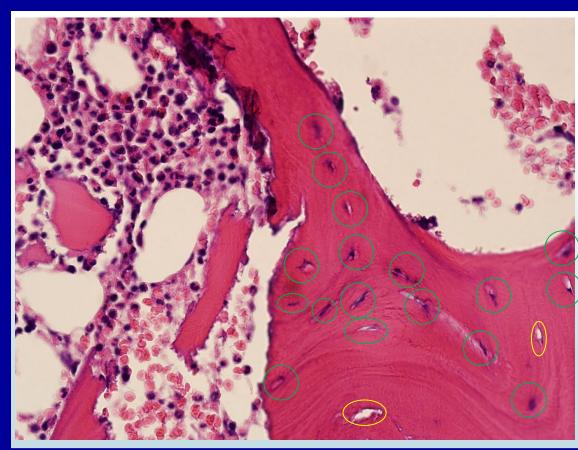


# RIBG Histological Results % filled lacunae

RIBG:82.7 ± 14.1%

Controls
 87.4% ± 7.5%

p = NS



Green = filled lacunae Yellow = empty lacunae



#### RIBG Histology Results-Marrow cellularity

	RIBG Group (n = 16)	Control Group (n = 16)		
Age (yrs, mean $\pm$ SD)	55.1 ± 8.9	$61.8 \pm 21.9$		
Sex (% female)	73	75		
Lacunae w osteocytes (%, mean $\pm$ SD)	$82.7 \pm 14.1$	$87.4 \pm 7.5$		
Trabeculae $w \ge 1$ viable osteocyte (%)	8/16: 90-100%	All 90-100%		
	6/16: 80-90%			
	2/16: 60-80%			
Marrow Cellularity (%, mean ± SD)	$30.5 \pm 19.0$	$45.3 \pm 18.8$		
Marrow Cellularity (%, range)	5 – 60	20 - 80		
Hypercellular	1/15	2/16		
Normocellular	5/15	15/16		
Hypocellular	10/15	0/16		

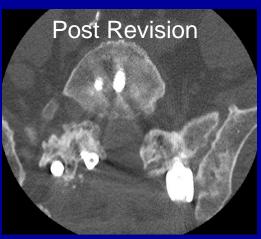
#### CT Scan Results after revison

#### Revision PSF:

- Pseudo repair
  - ≥100% solid
- PSF extension
  - >89% solid
- Combined
  - >94% solid









Pseudo case: Open facet joints, interbody lucency in high risk patient (left). After revision, facet joints and interbody fused (right image).



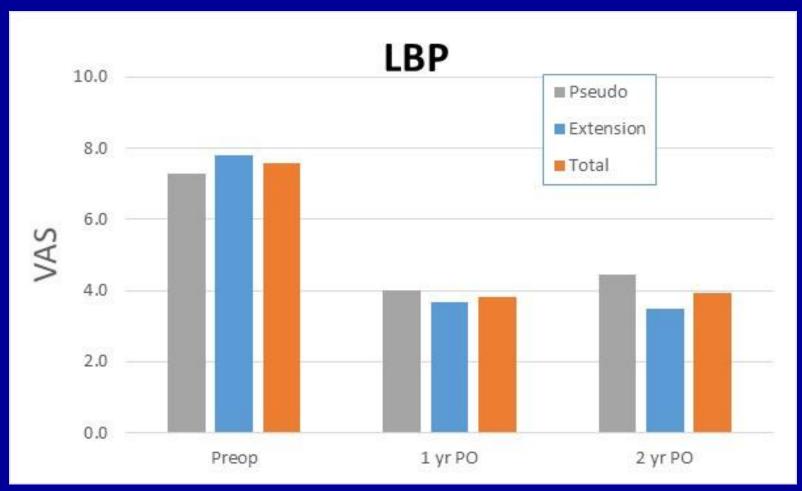
# CT scans (1 yr post-Revision) RIBG vs Controls (all consecutive pts)

Pseudo Repair							
Bonegraft Type	# patients	Age (yrs)	<u>Median # levels Sm</u>	nokers (%)	BMP (#/%)	BGS (#/%)	Solid PSF (CT)
Reconstructed Ilium (RIBG)	7	53.7 ± 12.8	1 (range 1-6)	5 (71%)	6 (86%)	4 (57%)	7 (100%)
Local autograft	6	58.3 ± 15.9	1 (range 1-2)	3 (50%)	0 0%)	2 (33%)	3 (50%)
Iliac bone autograft (IBG)	17	49.7 ± 17.0	1 (range 1-4)	7 (41%)	0 0%)	5 (29%)	12 (71%)
Bone Morphogenic Protein (BMP	) 22	56.6 ± 17.1	1 (range 1-3) 1	LO (45%)	22 (100%)	10 (45%)	19 (86%)
IBG + BMP	8	55.4 ± 15.6	1 (range 1-3)	4 (50%)	8 (100%)	5 (63%)	7 (88%)
Extension of PSF							
Reconstructed Ilium (RIBG)	9	56.3 ± 3.8	2 (range 1-6)	5 (56%)	4 (44%)	2 (22%)	8 (89%)
Local autograft	4	53.8 ± 12.2	1 (range 1)	1 (25%)	0 0%)	1 (25%)	4 (100%)
Iliac bone autograft (IBG)	19	56.5 ± 9.1	1 (range 1-3)	8 (40%)	0 0%)	5 (29%)	15 (79%)
Bone Morphogenic Protein (BMP	) 56	60.5 ± 15.0	1 (range 1-7)	19 (34%)	56 (100%)	12 (21%)	44 (79%)
IBG + BMP	1	52.6	1 (range 1) 1	l (100%)	1 (100%)	1 (100%)	1 (100%)

BGS = internal bone growth stimulator, CT = high-resolution CT scan, PSF = posterior spinal fusion, pseudo = pseudarthrosis

#### **Outcomes**

Outcomes: significant improvement but no difference between groups



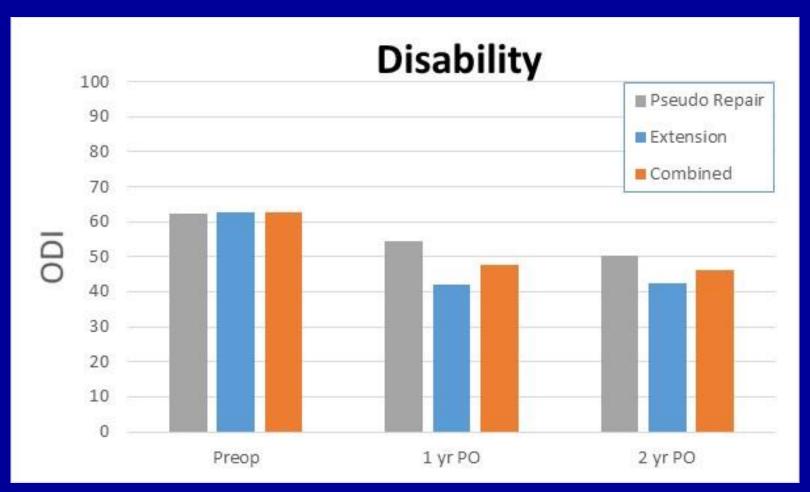
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#### **Discussion - Conclusions**

- RIBG site using allograft chips remodels into viable (primarily cancellous) bone.
- Marrow less cellular relative to normal controls.
- Filled lacunae = 83 ± 14% (normal bone, ~90%).
- High radiographic, CT, fusion rate, 94%, for complex revision patient population.
- Other bone growth supplements confound true clinical effectiveness of reharvested IBG.
- Modest outcomes improvements for complex revision patient population c/w prior reports.



### Thank You





