Appendix 1 Table J. Off-Label Comparative Study Radiographic Outcomes

	Study design	Comparisons No. pts (BMP dose)	Patient diagnosis	Surgical intervention	Successful outcome (%) (p-value)	Time to successful outcome mn ± SD (rng) (p-value)	Definition of successful outcome	Comment
Boden et al., 2002 USA (84) **Lumbar Spine**	Multicenter, nonblinded RCT	rhBMP2/CRM plus Texas Scottish Rite Hospital (TSRH) Spinal System (TSRHSS) n=11	single-level lumbar DDD	single-level primary instrumented posterolateral lumbar fusion plus rhBMP2 ICBG	24 mos. (22/27 pts) rhBMP2/CRM/TSRHSS 100	NR	Presence of bridging trabecular bone between the transverse processes, absence of motion, defined as 3 mm or less of translation and < 5 degrees of angular motion on flexion-extension views, and absence of radiolucent lines through the fusion mass Fusion evaluated by two independent radiologists who were unaware of treatment	By 12 mos. and continuing at 24 mos, the opacity of the ceramic CRM changed from a pale gray speckled pattern to a more uniform, well-marginated whiter mass
		(40 mg/pt) rhBMP2/CRM alone n=11			rhBMP2/CRM alone 100			
		(40 mg/pt) ICBG plus TSRHSS n=5			ICBG/TSRHSS 40 (p=0.018, 0.028 in BMP2 groups vs ICBG)			
Burkus et al., 2005 USA (85) **Lumbar Spine** Note: includes all pts from Burkus et al., 2002,	Multicenter, nonblinded RCT	rhBMP2 n=79 (8-12 mg/pt)	single-level lumbar lumbar DDD	primary single-level anterior lumbar fusion with a pair of threaded allograft cortical bone dowels (CBD) plus rhBMP2 or ICBG	6, 12, 24 mos rhBMP2 96, 99, 98	NR	Presence of bridging bone connecting adjacent vertebral bodies, either through the FRA or around the FRA, < 5 degrees of angular motion, ≤ 3 mm translation, and absence of radiolucent lines around > 50% of the	Fusion was deemed successful only if all criteria were met In the ICBG group, no patient had a fracture, migration, or extrusion of the FRA 14 (18%) of 79 patients in the rhBMP2 group
		ICBG N=52			ICBG 85, 89, 76 (p=0.047, 0.035, < 0.001)			

rec# 11510; same pts as Burkus et al., 2006, rec# 6640							graft Fusion evaluated by two independent radiologists who were unaware of treatment, a third was consulted for adjudication of disagreement	had transient localized areas of bone remodeling in the vertebral body adjacent to a FRA, visible between 3 and 12 mos. postsurgery, but resolved by 24 mos
Dimar et al., 2009 USA (86) **Lumbar Spine** Note: contains pts in Glassman et al., 2007, rec# 4040; Dimar et al, 2006 rec# 5480; Glassman et al., 2005, rec# 8040	Multicenter nonblinded RCT	rhBMP2/CRM n=239 (40 mg/pt) ICBG n=224	single-level lumbar DDD	single-level primary instrumented posterolateral lumbar fusion plus rhBMP2 or ICBG	6, 12, 24 mos rhBMP2/CRM 79, 88, 96 ICBG 65, 83, 89 (p=0.002, 0.107, 0.014)	NR	Presence of bridging trabecular bone between the transverse processes, absence of motion, defined as 3 mm or less of translation and < 5 degrees of angular motion on flexion-extension views, and absence of radiolucent lines through the fusion mass Fusion evaluated by two independent radiologists who were unaware of treatment, a third was consulted for adjudication of disagreement	Thin-cut CT showed progressive formation of bridging bone across the transverse processes
Glassman et al., 2007 USA (99) **Lumbar Spine**	Retrospective with historical control group	rhBMP2 n=91 (12 mg/pt) ICBG n=35	single- and multi-level lumbar DDD, degenerative scoliosis, postdiscectomy instability,	single- or multi-level primary or revision instrumented posterolateral lumbar fusion	rhBMP2 24 mos 46 of 48 (96)	NR	Plain radiographs: fusion mass graded as solid fusion, probabale fusion, or nonunion CT fusion rating	Fusion grade a composite score from 2 reviewers of CT scans

			spinal stenosis, adjacent level degeneration				scale: Grade 1=no fusion Grade 2=partial or limited unilateral fusion Grade 3=partial or limited bilateral fusion Grade 4=solid unilateral fusion Grade 5=solid bilateral fusion Fusion evaluated by two independent radiologists who were unaware of treatment	
Glassman et al., 2008 USA (87) **Lumbar Spine**	Multicenter nonblinded RCT	rhBMP2/ACS n=50 (dose not reported) ICBG n=52	single- or multi-level lumbar DDD	single- or multi-level primary instrumented posterolateral lumbar fusion plus rhBMP2 or ICBG	rhBMP2 86 Average CT fusion grade at 24 mos rhBMP2 4.3±1.3 ICBG 71 Average CT fusion grade at 24 mos ICBG 3.8±0.9 (p=0.030)	NR	CT fusion rating scale: Grade 1=no fusion Grade 2=partial or limited unilateral fusion Grade 3=partial or limited bilateral fusion Grade 4=solid unilateral fusion Grade 5=solid bilateral fusion Fusion evaluated independently by 3 orthopedic spine surgeons unaware of treatment	Fusion grade a composite score from 3 reviewers of CT scans
Haid et al., 2004 USA (88)	Multicenter, nonblinded RCT	rhBMP2 n=34 (4.2-8.4)	single-level lumbar DDD	single-level primary posterior lumbar	6, 12, 24 mos rhBMP2 93, 85, 92	NR	Presence of bridging bone connecting adjacent vertebral bodies, < 5 degrees	Secondary surgeries were classified as fusion failures regardless of

Lumbar Spine		ICBG N=33		interbody fusion (PLIF) interbody fusion cages plus rhBMP2 or ICBG	ICBG 93, 92, 78		of angular motion, ≤ 3 mm translation, and absence of radiolucent lines around > 50% of the graft Fusion evaluated by two independent radiologists who were unaware of treatment, a third was consulted for adjudication of disagreement	independent radiologic assessment New bone formation extending outside the disc space and into the spinal canal or neuroforamina was observed in 24 rhBMP2 (71) and 4 (12) ICBG recipients ($p < 0.0001$) but was not correlated with recurrence or increase in leg pain from the preoperative status
Johnsson et al., 2002 Sweden (92) **Lumbar Spine**	Multicenter nonblinded RCT	rhBMP7 n=10 (7 mg/pt)	single-level lumbar DDD	single-level primary uninstrumented posterolateral lumbar fusion with rhBMP7 or ICBG	Radiographic fusion 12 mos rhBMP7 60 bilateral bridging bone 30 partial bone formation 10 no bone formation	NR	Bone formation classified as radiographic evidence of bilaterally bridging bone, partial bone formation, or no bone formation	RSA analysis showed no significant differences in L5 stabilization or movement
		ICBG n=10			ICBG 80 bilateral bridging bone 20 partial bone formation			
Kanayama et al., 2006 Japan, Cleveland (93) **Lumbar Spine**	Multicenter nonblinded RCT	rhBMP7 n=9 (7 mg/pt)	single-level lumbar DDD	single-level primary instrumented posterolateral lumbar fusion with rhBMP7 or AGB/CRM	Radiographic fusion criteria at 15.3 mos rhBMP7 78 Surgical evidence of solid fusion rhBMP7 57 (4 of 7)	NR	Presence of bridging bone on CT scan in posterolateral lumbar area, ≤ 5 degrees of angulation and ≤ 2 mm of translation at the index level	No significant differences in fusion,but small pt numbers limit ersults
		AGB/CRM			Radiographic fusion			

		n=10			criteria at 15.3 mos AGB/CRM 90 Surgical evidence of solid fusion AGB/CRM 78 (7 of 9)			
Mummaneni et al., 2004 USA (100) **Lumbar Spine**	Retrospective single-center cohort study	rhBMP2/AGB n=25 (8.4 mg/pt) ICBG N=19	single- or multi-level lumbar DDD	single- or multi-level primary transforaminal lumbar interbody fusion (TLIF) with interbody fusion cages with rhBMP2 plus AGB or ICBG alone	rhBMP2/AGB 96 at average 8 mos. F/U ICBG 95 at average 11 mos. F/U	rhBMP2/AGB 3.6±2.0 (1-9) ICBG 6.4±2.4 (3-12)	Presence of bridging bone connecting adjacent vertebral bodies, lack of motion on dynamic flexion-extension radiographs, absence of halo around screws Fusion analysis method not mentioned	Only used plain radiographs for fusion studies
Pradhan et al., 2006 USA (101) **Lumbar Spine**	Prospective consecutive patient single-center cohort study	rhBMP2 n=9 (dose NR) ICBG n=27	single-level lumbar DDD	single-level primary anterior lumbar interbody fusion (ALIF) with femoral ring allograft (FRA) plus rhBMP2 or ICBG	24 mos rhBMP2 4 of 9 (44) Non-unions rhBMP 5 (56) 24 mos ICBG 17 of 27 (63) Non-unions ICBG 10 (37)	NR	Presence of bridging bone connecting adjacent vertebral bodies, either through the FRA or around the FRA, < 5 degrees of angular motion, ≤ 3 mm translation, and absence of radiolucent lines around > 50% of the graft Fusion evaluated by a radiologist who was unaware of treatment	Fusion was deemed successful only if all criteria were met Graft and endplate resorption reported to occur earlier and more aggressively in pts treated with rhBMP2 compared with ICBG, which may be related to number of non-unions and delayed unions
Singh et al., 2006 USA	Prospective single-center case-matched	rhBMP2/ICBG n=39 (12-36 mg/pt)	single- or multi-level lumbar DDD	single- or multi-level primary instrumented	24 mos rhBMP2/ICBG 94 (68 of 70 levels)	NR	Presence of continuous trabecular bone between	Fusion quality was subjectively assessed as excellent in 92% of

(102) **Lumbar Spine**	cohort study	 ICBG N=11		posterolateral lumbar fusion with rhBMP2 plus ICBG or ICBG alone	 ICBG 77 (17 of 22 levels) ($p < 0.05$)		intertransverse processes, cortication at the peripheral edge of the fusion mass, and absence of identifiable radiographic cleft on CT assessment Fusion evaluated by two orthopedic surgeons and a radiologist, all unaware of treatment	rhBMP2/ICBG recipients and 27% of ICBG recipients ($p < 0.05$)
Slosar et al., 2007 USA (103) **Lumbar Spine**	Prospective consecutive patient single-center cohort study	rhBMP2 n=45 (3-9 mg/pt) ALG N=30	single- or multi-level lumbar DDD	single- or multi-level primary instrumented anterior lumbar interbody fusion (ALIF) with femoral ring allograft (FRA) plus rhBMP2 or allograft bone chips (ALG)	6, 12, 24 mos rhBMP2 79, 96, 99 ALG 23, 73, 82 ($p < 0.001$ at all times)	NR	Molinari-Bridwell grading (Molinari et al., 1999) scale used: Grade 1: fused with remodeling and trabeculae present Grade 2: Graft intact, not fully remodeled and incorporated, no lucency Grade 3: Graft intact, potential lucency present at top or bottom of graft Grade 4: Fusion absent with collapse/resorption of graft Grades 1-2 were considered fused, Grades 3-4	No osteolysis or fragmentations of FRA were observed

							considered not fused All studies were reviewed by independent reviewers uaware of treatment	
Vaccaro et al., 2008 USA (94) **Lumbar Spine**	Multicenter nonblinded RCT	rhBMP7 n=207 (7 mg/pt)	single-level lumbar DDD	single-level primary uninstrumented posterolateral lumbar fusion with rhBMP7 or ICBG	Bridging bone (CT) 36+ mos rhBMP2 75	NR	Presence of new bone formation bridging across the transverse processes, angulation ≤ 5 degrees, and ≤ 3 mm of translation were required Fusion evaluated independently by 2 primary spine surgeons unaware of treatment, a third was consulted for adjudication of disagreement	Overall radiographic comprised 3 components necessary to define fusion No significant differences seen in fusion parameters at 36+ mos. F/U
					≤ 5 degrees angulation (plain film) rhBMP7 69			
					≤ 3 mm translation (plain film) rhBMP7 76			
		ICBG n=86			Bridging bone (CT) 36+ mos ICBG 77			
					≤ 5 degrees angulation (plain film) ICBG 68			
					≤ 3 mm translation (plain film) ICBG 75			
Vaccaro et al., 2008 USA (95) **Lumbar Spine** Note:	Multicenter, nonblinded RCT	rhBMP7 n=24 (7 mg/pt)	single-level lumbar DDD	single-level primary uninstrumented posterolateral lumbar fusion with rhBMP7 or ICBG	Solid fusion 48 mos rhBMP7 69 (11 of 16 with data)	NR	Complete bridging bone between transverse processes, ≤ 5 degrees of angulation and ≤ 2 mm of translation	Both groups showed equivalent reductions in disc height as well as angular and translational motion at the treated level
					Bridging bone 48 mos rhBMP7			

Long-term F/U study that includes all pts from Vaccaro et al., 2004, (184), and Vaccaro et al., 2005, (185)		ICBG n=12			81 (13 of 16 with data) Solid fusion ICBG 50 (3 of 6 with data) Bridging bone 48 mos ICBG 50 (3 of 6 with data)		Fusion evaluated independently by 2 neuroradiologists unaware of treatment, a third was consulted for adjudication of disagreement	
Baskin et al., 2003 USA (89) **Cervical Spine**	Multicenter, nonblinded RCT	rhBMP2/ALG n=18 (0.6-1.2 mg/pt) ICBG/ALG n=15	single- or two-level cervical DDD	single- or two-level primary instrumented ACDF with rhBMP2/ALG or ICBG/ALG	6, 12, 24 mos rhBMP2/ALG 100 at all times ICBG/ALG 100 at all times	NR	Plain radiograph: < 4 degrees difference in angular motion between flexion and extension, no radiolucency > 2 mm thick covering > 50% of the inferior or superior graft surface, presence of bridging trabecular bone CT: presence of bridging trabecular bone	Two pts in rhBMP2/ALG and one in the ICBG/ALG group demonstrated bone formation immediately anterior to segments adjacent to the index level
Butterman et al., 2008 (104) **Cervical Spine**	Prospective nonrandomized cohorts of consecutive patients	rhBMP2/CRA n=30 (0.9-3.7 mg/pt) ICBG n=36	single- or multiple-level cervical DDD	single- or multi-level primary instrumented or uninstrumented ACDF with rhBMP2/CRA or ICBG	NR	NR	Plain films: Presence of bridging trabecular bone across disc space, < 1 mm gapping of spinous processes on flexion-extension films and selected high-resolution CT scans	2 pseudarthroses in ICBG group, 1 in the rhBMP2/CRA group
Crawford et al., 2009 USA	Retrospective cohort of consecutive	rhBMP2/BGE n=41 (4.2-12 mg/pt)	single- or multi-level posterior cervical	single- or multi-level instrumented	NR	NR	NR	

(105) **Cervical Spine**	patients	ICBG n=36	stenosis, ACDF nonunion, or unstable spondylosis	posterior cervical spinal fusion with rhBMP2/BGE or ICBG				
Smucker et al., 2006 (106) **Cervical Spine**	Retrospective case-control	rhBMP2/CRA n=69 (dose NR) CRA n=165	NR	single- or multi-level instrumented ACDF with rhBMP2/CRA or CRA alone	NR	NR	NR	
Vaidya et al., 2007 (107) **Cervical Spine**	Retrospective cohort of consecutive patients	rhBMP2 n=22 (1-3 mg/pt) ALG/DBM n=24	single- or multiple-level cervical DDD with radiculopathy or myelopathy	single- or multi-level primary instrumented ACDF with interbody fusion cages rhBMP2 on ACS or ALG/DBM	rhBMP2 100 ALG/DBM 96	NR	For the rhBMP2 group, bone formation was assessed as no new bone, visible new bone, possible fusion, and probable fusion For the ALG/DBM group fusion was assessed at the graft endplate junction, classified as not united, possibly united, and probably united	End plate resorption was noted in 100% of the levels where rhBMP2 was used, starting at 1.5 mos. and lasting until 6 mos
Boraiah et al., 2009 USA (108) **Acute Tibial Fractures**	Retrospective case series	rhBMP2 (1) n=17 (12 mg/pt) (2) n=23 no BMP	Complex tibial plateau fractures	Surgery for Acute traumatic tibial plateau fractures	NR	NR	NR	Data was collected an analyzed to look at prediction of HO
Jones et al., 2006 USA (90) **Acute**	Multi-center prospective RCT	rhBMP2 (1) n=15 (12 mg/pt with allograft bone chips	Diaphyseal tibial fracture with cortical defects	Reconstruction of diaphyseal tibial fractures with cortical defect	BMP 13(87%)	Median time to healing BMP 184 days	Radiographic evidence of extracortical bridging callus on three of the four cortices as	

Tibial Fractures		(2) n=15 autogenous bone graft			No BMP 10(67%)	No BMP 176 days	viewed on anteroposterior and lateral radiographs	
Ristiniemi et al., 2007 Finland (110) **Acute Tibial Fractures** (same pts as rec#4560)	Retrospective cohort of matched patients	Rh-BMP7 N=20 Matched Zone 43 fracture (OREF) N=20	Distal tibial fracture (OTA zone 43) treated with external fixation	Distal tibial fracture (OTA zone 43) treated with external fixation by BMP7 and graft	All fractures in both groups united	BMP: 15.7 weeks (7 to 43) Matched: 23.5 weeks (11 to 63) P=.002	Fractures classified as united based on presence of briding callus at 3 of 4 corticies and appearance of trabecular bridging and healing	
Bilic et al., 2006 Croatia, Netherlands (96) **Miscella-neous Off-Label Uses**	Single-center, unblinded RCT	rhBMP7/AGB n=6 (3.5 mg/pt) rhBMP7/ALG n=6 (3.5 mg/pt) ICBG n=6	symptomatic proximal pole scaphoid nonunion	revision of nonunion	Radiographic bridging 1, 2, 24 mos rhBMP7/AGB 70-95, 90-100, 100 Mean sclerotic bone area (mm2) 3, 9, 24 mos rhBMP7/AGB 74±14, 45±11, 32±7 Radiographic bridging 1, 2, 24 mos rhBMP7/ALG 60-80, 75-90, 100 Mean sclerotic bone area (mm2) 3, 9, 24 mos rhBMP7/ALG 104±13, 77±8, 56±12 Radiographic bridging 1, 2, 24 mos ICBG 60-80, 75-90, 100 Mean sclerotic bone area (mm2) 3, 9, 24 mos	NR	Radiographic determination of graft replacement by newly formed, well-incorporated bone, with full mineralization at end of F/U	All three groups showed significant ($p < 0.05$) reduction of sclerotic bone area at 3 mos, but only the two rhBMP7-treated groups had significant reductions at 9 and 24 mos.

					ICBG 138±15, 119±19, 112±9 (p < 0.05 rhBMP7/AGB, rhBMP7/ALG vs ICBG at 24 mos)			
Dickinson et al., 2008 USA (91) **Miscella-neous Off-Label Uses**	Single-center RCT	rhBMP2/ACS n=9 (dose not given)	unilateral cleft lip-palate with an alveolar cleft defect	repair of unilateral cleft lip-palate with an alveolar cleft defect	Percent alveolar defect filled 12 mos rhBMP2/ACS 95	NR	Panorex and 3-D CT scores ranged from 0-3, with 0 representing minimum or no bone defect mineralization, 3 representing 75-100% mineralization Periapical film radiographic outcome scored using 4-point grading system, with 0 being no healing, 4 being total healing on periapical film Defect filling was evaluated by three blinded reviewers	
					Mean Panorex score 12 mos rhBMP2/ACS 2.9±0.3			
					Mean 3-D CT scan score 12 mos rhBMP2/ACS 2.9±0.3			
					Mean periapical film score 12 mos rhBMP2/ACS 3.4±0.3			
		ICBG n=12			Percent alveolar defect filled 12 mos ICBG 63 (p < 0.01)			
					Mean Panorex score 12 mos ICBG 2.0±0.8 (p < 0.05)			
					Mean 3-D CT scan score 12 mos			

					ICBG 2.0±0.8 (p < 0.05) Mean periapical film score 12 mos ICBG 2.8±0.4 (p < 0.05)			
Ekrol et al., 2008 UK (97) **Miscella-neous Off-Label Uses**	Prospective randomized cohort	rhBMP2 Non bridging external fixation N=4	Osteotomy of the distal radius for symptomatic malunion (with and without external fixation)	Osteotomy of the distal radius for symptomatic malunion (with and without external fixation) with RhBMP-7 and autologous bone graft	RhBMP2 Non bridging external fixation: Partial union 3, nonunion 1 (0%)	rhBMP2 Non bridging external fixation: 13 weeks (8-18)	Defect considered healed when at least 75% of the defect had been filled with trabecular bone on both radiological views	
		Bone graft Non bridging external fixation N=6			Bone graft Non bridging external fixation: 6 pts successful union (100%)	Bone graft Non bridging external fixation: 7 weeks (4-12) P=.05 (external fixation bmp vs graft)		
		RhBMP-7 internal fixation w/ pi-plate N=10			RhBMP-7 internal fixation w/ pi-plate: 6 partial union (dorsal defects), 2 non-union (20%)	RhBMP-7 internal fixation w/ pi-plate: 18 weeks (4-46)		
		Bone graft internal fixation w/ pi-plate N=10			Bone graft internal fixation w/ pi-plate: 10 successful union (100%) p value comparing bone graft and RhBMP-7 internal fixation w/ pi-	Bone graft internal fixation w/ pi-plate: 7 weeks (4-13) P=.019 (pi-		

					plate partial union=.015	plate fixation bmp vs graft)		
Geesink et al., 1999 Netherlands (98) **Miscella-neous Off-Label Uses**	Prospective double-blind randomized study	Untreated N=6	High tibial osteotomy	High tibial osteotomy with three osteoinductive materials	New bone formation at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,0,1,1,2,3	NR	Response was classified as demonstrating bone formation that bridged the distal and proximal parts of fibular defect, bone formation that doesn't bridge defect, and no bone formation	
					New bone formation and bridging at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,0,0,0,0,0			
		DMB N=6			New bone formation at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,6,6,6,6,6			
					New bone formation and bridging at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,1,4,4,4,4			
		Collagen type I N=6			New bone formation at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,2,3,3,2,2			
					New bone formation and bridging at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,0,0,0,0,0			
		OP-1 (2.5mg) with Collagen type I N=6			New bone formation at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,5,5,5,5,5			

					New bone formation and bridging at 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, and 12 mths: 0,4,5,4,4,5			
Karrholm et al., 2006 UK (111) **Miscella-neous Off-Label Uses**	Single-center case-control	Cups rhBMP7/ALG (1 g/pt) n=10	required revision of total hip arthroplasty	impaction grafting for revision of hip arthroplasty	Cups No. hips with radiolucent lines at 5 yrs No. hips with graft remodeling (total) at 5 yrs	NR	Graft remodeling classified according to most common appearance (pattern found in at least 2-3 of 3 modified Charnley-DeLee regions with equal size.	
					AP view (% total interface) 0, < 50, 51-99, 100 rhBMP7/ALG 2, 5, 2, 1			
					Lateral view (% interface) 0, < 50, 51-99, 100 rhBMP7/ALG 3, 2, 2, 1			
					AP view rhBMP7/ALG 10			
					Lateral view rhBMP7/ALG 6			
		Cups ALG n=10			AP view (% total interface) 0, < 50, 51-99, 100 ALG 2, 6, 2, 0			
					Lateral view (% interface) 0, < 50, 51-99, 100 ALG 5, 2, 3, 0			
					AP view			

					ALG 9			
					Lateral view ALG 8			
		Stems rhBMP7/ALG (1 g/pt) n=11			Stems No. hips with radiolucent lines at 5 yrs			
					AP view (% total interface) 0, < 50, 51-99, 100 rhBMP7/ALG 2, 7, 0, 0			
					Lateral view (% interface) 0, < 50, 51-99, 100 rhBMP7/ALG 5, 4, 0, 0			
					No. hips with graft remodeling (total) at 5 yrs			
					AP view rhBMP7/ALG 9			
					Lateral view rhBMP7/ALG 6			
		Stems ALG n=30			Stems AP view (% total interface) 0, < 50, 51-99, 100 ALG 9, 18, 12, 12			
					Lateral view (% interface) 0, < 50, 51-99, 100 ALG			

					11, 11, 2, 1 AP view ALG 29 Lateral view ALG 27			
Maeda et al., 2009 USA, Japan (109) **Miscellaneous Off-Label Uses**	Cohort study with nonconcurrent control group	rhBMP2/BGE n=23 (64-320 mg/pt) ICBG n=32	spinal deformity	primary instrumented posterior spinal fusion from thoracic spine to the sacrum or ilium, or anterior fusion between same locations using interbody fusion cage	Solid fusion rhBMP2/BGE 96 Cobb angle correction rhBMP2/BGE 51 Solid fusion ICBG 72 (p=0.057) Cobb angle correction ICBG 42	NR	Plain anteroposterior and lateral standing radiographs used to assess fusion, based on absence of pseudarthrosis as defined by: loss of fixation, progression of deformity, disc space collapse within fused portion, motion across the suspected pseudarthrosis; suspicion of nonunion was confirmed by CT scan	