

Appendix 1 Table L. Off-Label Comparative Study Pain Outcomes

Investigator (yr, country, ref #) Surgical Site	Study design	Comparisons No. pts (BMP dose)	Patient diagnosis	Surgical intervention	Outcome measure mean score (p-value)	Percent improved or success (p-value)	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	Oswestry DI Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM/TSRHSS ~3, ~18, ~20, ~13	Oswestry DI ≥ 15% improvement 1.5, 3, 6, 17 mos rhBMP2/CRM/TSRHSS ~38, ~80, ~80, ~65	All pain outcomes showed significant improvement in both groups at 17-24 mos. but no significant intergroup differences except for SF- 36 score at 17 mos
					Back pain Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM/TSRHSS ~6, ~8, ~7, ~5		
					Leg pain Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM/TSRHSS ~3, ~4, ~1, ~3		
					SF-36 bodily pain subscale Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM/TSRHSS ~3, ~10, ~23, ~15		
		Oswestry DI Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM alone ~19, ~22, ~25, ~29			rhBMP2 alone ~88, ~88, ~88, ~100		
		Back pain Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM alone ~8, ~9, ~9, ~10					
		(40 mg/pt) rhBMP2/CRM alone n=11					

					<p>Leg pain Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM ~8, ~9, ~7, ~9</p>		
					<p>SF-36 bodily pain subscale Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM alone ~22, ~32, ~35, ~35</p>		
		(40 mg/pt) ICBG plus TSRHSS n=5			<p>Oswestry DI Mean score improvement (points) 1.5, 3, 6, 17 mos ICBG/TSRHSS ~10, ~15, ~17, ~25</p>	ICBG/TSRHSS ~80, ~60, ~80, ~80	
					<p>Back pain Mean score improvement (points) 1.5, 3, 6, 17 mos ICBG/TSRHSS ~7, ~5, ~4, ~5</p>		
					<p>Leg pain Mean score improvement (points) 1.5, 3, 6, 17 mos rhBMP2/CRM/TSRHSS ICBG/TSRHSS ~7, ~3, ~3, ~4</p>		
					<p>SF-36 bodily pain subscale Mean score improvement (points) 1.5, 3, 6, 17 mos ICBG/TSRHSS ~3, ~10, ~23, ~15 (rhBMP2/CRM alone, p=0.049 vs the other 2 groups)</p>		
Burkus et al., 2005 USA (85) Lumbar Spine Note: includes all	Multicenter, nonblinded RCT	rhBMP2 n=79 (8-12 mg/pt)	single-level lumbar DDD	primary single- level anterior lumbar fusion with a pair of threaded			Both groups had statistically significant improvement in the mean ODI,
		ICBG					

pts from Burkus et al., 2002, rec# 11510; same pts as Burkus et al., 2006, rec# 6640		N=52		allograft cortical bone dowels (CBD) plus rhBMP2 or ICBG			back, and leg pain scores compared to preoperative values Statistically significant intergroup differences favoring rhBMP2 seen in all three indexes at specific times
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- or multi-level lumbar DDD	single-level primary instrumented posterolateral lumbar fusion plus rhBMP2 or ICBG		NR	All pain outcomes showed significant improvement in both groups at 24 mos. but no significant intergroup differences
Glassman et al., 2007 USA (99) Lumbar Spine	Retrospective with historical control group	rhBMP2 n=91 (12 mg/pt) ICBG n=35	single-level lumbar DDD	single- or multi-level primary or revision instrumented posterolateral lumbar fusion	NR	NR	Study only reported fusion data
Glassman et al., 2008 USA (87) Lumbar Spine	Multicenter nonblinded RCT	rhBMP2/ACS n=50 (dose not reported)	single-level lumbar DDD	single- or multi-level primary instrumented posterolateral lumbar fusion	Oswestry DI Mean score improvement (points) 3, 6, 12, 24 mos rhBMP2 14, 18, 19, 15	NR	Mean pain scores were similar in both groups at all time intervals,

				plus rhBMP2 or ICBG	<p>Back pain Mean score improvement (points) 1.5, 6, 12, 24 rhBMP2 4.3, 4.1, 4.1, 3.1</p> <p>Leg pain Mean score improvement (points) 1.5, 6, 12, 24 mos rhBMP2 4.6, 4.4, 3.8, 3.6</p> <p>Oswestry DI Mean score improvement (points) 3, 6, 12, 24 mos ICBG 13, 17, 18, 13</p> <p>Back pain Mean score improvement (points) 1.5, 6, 12, 24 ICBG 4.0, 4.0, 3.9, 3.0</p> <p>Leg pain Mean score improvement (points) 1.5, 6, 12, 24 mos ICBG 4.1, 4.2, 3.9, 3.1</p> <p>Iliac crest pain postharvest NR</p>		with statistically significant improvement compared to preoperative mean scores but no significant intergroup differences
		ICBG n=52					
Haid et al., 2004 USA (88) Lumbar Spine	Multicenter, nonblinded RCT	rhBMP2 n=34 (4.2-8.4)	single- or multi- level lumbar DDD	single-level primary posterior lumbar interbody fusion (PLIF) interbody fusion cages plus rhBMP2 or	<p>Oswestry DI Mean score improvement (points) 24 mos rhBMP2 30</p> <p>Back pain Mean score improvement (points) 24 mos rhBMP2</p>	Oswestry DI ≥ 15% improvement 24 mos rhBMP2 69	Both groups had statistically significant improvements in mean ODI, back, and leg pain at all times compared to preoperative

				ICBG	9		values
					Leg pain Mean score improvement (points) 24 mos rhBMP2 7.7		
		ICBG N=33			Oswestry DI Mean score improvement (points) 24 mos ICBG 25	ICBG 56	
					Back pain Mean score improvement (points) 24 mos ICBG 4.5 (p=0.009)		
					Leg pain Mean score improvement (points) 24 mos ICBG 6.5		
					Iliac crest pain postharvest Mean score (points) 24 mos 5.5		
					% with pain at 24 mos 60		
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	NR Iliac crest pain	Subjective evaluation of back pain 12 mos rhBMP7 None (4 pts) Minor w/out medication (4 pts) Major with medication (2)	Patients had similar pain outcomes, but no statistical analysis was done
		ICBG n=10				Subjective evaluation of back pain	

						12 mos ICBG None (5 pts)	
						Minor w/out medication (2 pts)	
						Major with medication (3 pts)	
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	Oswestry DI Mean score improvement (points) 3, 6, 9, 12 mos rhBMP7 ~15, ~23, ~16, ~17	NR	Both groups had significant decreases in pain from baseline (p < 0.05, ANOVA), but NSD between groups
		AGB/CRM n=10			AGB/CRM ~17, ~31, ~24, ~24		
Mummaneni et al., 2004 USA (100) Lumbar Spine	Retrospective single-center cohort study	rhBMP2/AGB n=25 (8.4 mg/pt)	single-level lumbar DDD	single- or multi- level primary transforaminal lumbar interbody fusion (TLIF) with interbody fusion cages with rhBMP2 plus AGB or ICBG alone	Prolo Scale Pain subscale Mean score at F/U (points) rhBMP2/AGB 3.8±0.9	NR	Statistical analysis not done
		ICBG N=19			Prolo Scale Pain subscale Mean score at F/U (points) ICBG 4.0±0.7		
					% with pain 6 mos 58		
					Mean pain score (points) 6 mos 5		
Pradhan et al., 2006 USA (101) Lumbar Spine	Prospective consecutive patient single- center cohort study	rhBMP2 n=9 (dose NR)	single- and multi-level lumbar DDD, degenerative scoliosis, postdiscectomy	single-level primary anterior lumbar interbody fusion (ALIF) with femoral	NR	NR	Study only reported fusion data
		ICBG n=27			iliac crest pain NR		

			instability, spinal stenosis, adjacent level degeneration	ring allograft (FRA) plus rhBMP2 or ICBG			
Singh et al., 2006 USA (102) Lumbar Spine	Prospective single-center case-matched cohort study	rhBMP2/ICBG n=39 (12-36 mg/pt)	single- or multi-level lumbar DDD	single- or multi-level primary instrumented posterolateral lumbar fusion with rhBMP2 plus ICBG or ICBG alone	NR	NR	
		ICBG N=11			Iliac crest pain NR		
Slosar et al., 2007 USA (103) Lumbar Spine	Prospective consecutive patient single-center cohort study	rhBMP2 n=45 (3-9 mg/pt)	single-level lumbar 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)	Oswestry DI Mean score improvement (points) 6, 12, 24 mos rhBMP2 27, 30, 33	NR	Both groups had statistically significant improvements in mean ODI and NRS at all times compared to preoperative values
					NRS (undefined) Mean score improvement (points) 6, 12, 24 mos rhBMP2 4.2, 4.7, 4.8		
		ALG N=30			Oswestry DI Mean score improvement (points) 6, 12, 24 mos ALG 17, 26, 30 (p < 0.001 at 6 mos)		
		NRS (undefined) Mean score improvement (points) 6, 12, 24 mos ALG 2.8, 4.4, 4.3 (p < 0.001 at 6 mos)					
Vaccaro et al., 2008 USA (94)	Multicenter nonblinded RCT	rhBMP7 n=207 (7 mg/pt)	single-level lumbar DDD	single-level primary uninstrumented posterolateral	Oswestry DI mean percent improvement from baseline 36+ mos rhBMP7 47	Modified Overall Success 36+ mos rhBMP7 47	Both groups had significant decreases in pain from

Lumbar Spine				lumbar fusion with rhBMP7 or ICBG	52	baseline levels	
					VAS scores 36+ mos NSD		Oswestry DI ≥ 20% improvement 36+ mos rhBMP7 69
					SF-36 scores NSD		
					Oswestry DI mean percent improvement from baseline 36+ mos ICBG 54		Modified Overall Success 36+ mos ICBG 47 (p for noninferiority=0.025)
					Iliac crest pain postharvest % with pain 12, 24, 36+ mos 44, 45, 35		Oswestry DI ≥ 20% improvement 36+ mos ICBG 77
					Mean pain score (points) 1.5, 12, 24, 36+ mos 2.1, 1.6, 1.2, 1.1		
Vaccaro et al., 2008 USA (95) Lumbar Spine Note: Long-term F/U study that includes all pts from Vaccaro et al., 2004, (184), and Vaccaro et al., 2005, (185)	Multicenter, nonblinded RCT	rhBMP7 n=24 (7 mg/pt)	single- or multi-level lumbar DDD	single-level primary uninstrumented posterolateral lumbar fusion with rhBMP7 or ICBG	Oswestry DI mean score NR	Overall success is a composite measure comprising definitive spinal fusion, minimum 20% improvement in Oswestry DI, and absence of surgical retreatment	
							Oswestry DI ≥ 20% improvement 48 mos rhBMP7 74 (14 of 19 with data) (95% CI, 49, 91)
					Overall success 48 mos rhBMP7 62 (10 of 16 with data)		
		ICBG n=12			Iliac crest pain NR	Oswestry DI ≥ 20% improvement 48 mos ICBG	

						57 (4 of 7 with data) (95% CI, 18, 90)	
						Overall success 48 mos ICBG 33 (2 of 6 with data)	
						Overall success 48 mos, LOCF analysis ICBG 25 (95% CI, 6-57)	
Baskin et al., 2003 USA (89) Cervical Spine	Multicenter, nonblinded RCT	rhBMP2/ALG n=18 (0.6-1.2 mg/pt)	single- or two- level cervical DDD	single- or two- level primary instrumented ACDF with rhBMP2/ALG or ICBG/ALG	Neck Disability Index Mean score improvement (points) 1.5, 3, 6, 12, 24 mos rhBMP2/ALG 37, 39, 48, 46, 53	Neck pain 24 mos rhBMP2/ALG 100	Both groups showed significant improvements from baseline, but there were no significant differences between groups in mean score or rates
					Neck pain Mean score improvement (points) 1.5, 3, 6, 12, 24 mos rhBMP2/ALG 11, 11, 11, 12, 13		
					Arm pain Mean score improvement (points) 1.5, 3, 6, 12, 24 mos rhBMP2/ALG 14, 14, 15, 14, 14		
		Neck Disability Index Mean score improvement (points) 1.5, 3, 6, 12, 24 mos ICBG/ALG 33, 34, 39, 41, 37 (p < 0.03 at 24 mos)			ICBG/ALG 100		
		Neck pain Mean score improvement (points) 1.5, 3, 6, 12, 24 mos ICBG/ALG 7, 8, 10, 9, 9					
ICBG/ALG n=15	Arm pain						

					<p>Mean score improvement (points) 1.5, 3, 6, 12, 24 mos ICBG/ALG 9, 8, 10, 10, 8 ($p < 0.03$ at 24 mos)</p> <p>Iliac crest pain postharvest 1.5, 6, 24mos Pain reported at each time, but not quantified</p>		
Butterman et al., 2008 (104) Cervical Spine	Prospective nonrandomized cohorts of consecutive patients	rhBMP2/CRA n=30 (0.9-3.7 mg/pt)	single- or multiple-level cervical DDD	single- or multi- level primary instrumented or uninstrumented ACDF with rhBMP2/CRA or ICBG	Oswestry Disability Index Mean score improvement (points) 7-12, 13-24, 25-36 mos rhBMP2/CRA ~14, ~25, ~30	NR	Both groups showed significant improvements from baseline, but there were no significant differences between groups in mean score or rates
					Neck pain Mean score improvement (points) 7-12, 13-24, 25-36 mos rhBMP2/CRA ~4, ~4.5, ~5		
					Arm pain Mean score improvement (points) 7-12, 13-24, 25-36 mos rhBMP2/CRA ~3.3, ~4.2, ~5.5		
					Narcotic pain medication use (%) preop, 7-12, 13-24, 25-36 mos rhBMP2/CRA 53, 30, 23, 10		
		ICBG n=36			Oswestry Disability Index Mean score improvement (points) 7-12, 13-24, 25-36 mos ICBG ~11, ~17, ~31		
		Neck pain Mean score improvement (points) 7-12, 13-24, 25-36 mos ICBG ~4, ~4, ~5					
		Arm pain Mean score improvement (points) 7-12, 13-24, 25-36 mos ICBG ~3.9, ~3.8, ~4.8					

					Narcotic pain medication use (%) preop, 7-12, 13-24, 25-36 mos ICBG 61, 39, 19, 6		
					Iliac crest pain postharvest		
Crawford et al., 2009 USA (105) Cervical Spine	Retrospective cohort of consecutive patients	rhBMP2/BGE n=41 (4.2-12 mg/pt) ICBG n=36	single- or multi- level posterior cervical stenosis, ACDF nonunion, or unstable spondylosis	single- or multi- level instrumented posterior cervical spinal fusion with rhBMP2/BGE or ICBG	NR Iliac crest pain postharvest	NR	
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	
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	Oswestry Disability Index Mean score improvement (points) 0.5, 1.5, 3, 6, 12, 24 mos rhBMP2 -3.6, 6, 8, 8, 14, 24 Neck pain Mean score improvement (points) 0.5, 1.5, 3, 6, 12, 24 mos rhBMP2 2, 2, 2, 2, 3, 4 Arm pain Mean score improvement (points) 0.5, 1.5, 3, 6, 12, 24 mos rhBMP2 1, 1, 2, 2, 3, 4 Oswestry Disability Index Mean score improvement (points) 0.5, 1.5, 3, 6, 12, 24 mos ALG/DBM	NR	Both groups showed significant improvements from baseline, but there were no significant differences between groups in mean score or rates

					2, 6, 10, 21, 28, 33		
					Neck pain Mean score improvement (points) 0.5, 1.5, 3, 6, 12, 24 mos ALG/DBM 4, 4, 4, 4, 5, 6		
					Arm pain Mean score improvement (points) 0.5, 1.5, 3, 6, 12, 24 mos ALG/DBM 3, 4, 3, 5, 5, 5		
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 Iliac crest pain postharvest NR	NR	
Jones et al., 2006 USA (90) Acute Tibial Fractures	Multi-center prospective RCT	rhBMP2 (1) n=15 (12 mg/pt with allograft bone chips) (2) n=15 autogenous bone graft	Diaphyseal tibial fracture with cortical defects	Reconstruction of diaphyseal tibial fractures with cortical defect	NR Iliac crest pain postharvest % with pain at 5 days-4.5 mos 100, 1 had residual pain at 12 mos	NR	
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	Distal tibial fracture (OTA zone 43) treated with external fixation	Distal tibial fracture (OTA zone 43) treated with external fixation by BMP7 and graft	Iowa Ankle Score: BMP: 84(70 to 100) Restriction in Range of motion Dorsiflexion (1) -12 (-42-5) Plantar flexion (1) -10 (-50-5) Iowa Ankle Score:	NR	

		43 fracture (OREF) N=20			Matched: 81.6 (46 to 98) P=.6		
					Restriction in Range of motion Dorsiflexion (2) -8 (-33-6) P-value 0.7		
					Plantar flexion (2) -6 (-20-8) P-value 0.3		
					Iliac crest pain postharvest NR		
Bilic et al., 2006 Croatia, Netherlands (96) Miscellaneous Off-Label Uses	Single-center, unblinded RCT	rhBMP7/AGB n=6 (3.5 mg/pt)	symptomatic proximal pole scaphoid nonunion	revision of nonunion	Pain at rest 4, 12 mos 0 in all three groups	NR	Pain score range 0-100 points
					Pain during maximal grip 4, 12 mos rhBMP7/AGB 0, 3±1		
					Pain in maximal dorsiflexion 4, 12 mos rhBMP7/AGB 0, 6±1		
		rhBMP7/ALG n=6 (3.5 mg/pt)			Pain during maximal grip 4, 12 mos rhBMP7/ALG 3±1, 0		
					Pain in maximal dorsiflexion 4, 12 mos rhBMP7/ALG 3±1, 0		
					Pain during maximal grip 4, 12 mos ICBG 5±1, 6±1		
					Pain in maximal dorsiflexion 4, 12 mos ICBG		

					15±2,11±2		
					Iliac crest pain postharvest Patients in both autograft groups reported pain, but not quantified		
Dickinson et al., 2008 USA (91) Miscellaneous 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	NR	NR	
		ICBG n=12			Iliac crest pain postharvest % with pain 0, 6 mos 100, 25		
Ekrol et al., 2008 UK (97) Miscellaneous 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	Pain (10 cm VAS mean) at pre-op, 52 wks, and % change: rhBMP2 Non bridging external fixation: 4,3,25%	rhBMP2 Non bridging external fixation: 25% improvement	
		Bone graft Non bridging external fixation N=6			Bone graft Non bridging external fixation: 5,3,30% NS p value	Bone graft Non bridging external fixation: 30% improvement	
		RhBMP-7 internal fixation w/ pi-plate N=10			RhBMP-7 internal fixation w/ pi-plate: 5,2,60%	RhBMP-7 internal fixation w/ pi-plate: 60% improvement	
		Bone graft internal fixation w/ pi-plate N=10			Bone graft internal fixation w/ pi-plate 5,4,20% NS p value	Bone graft internal fixation w/ pi-plate 20% improvement	
					Iliac crest pain postharvest	No significant P values	
Geesink et al., 1999 Netherlands (98) Miscellaneous Off-Label Uses	Prospective double-blind randomized study	Untreated N=6	High tibial osteotomy	High tibial osteotomy with three osteoinductive materials	Severity of pain on fibular osteotomy 1 wk, 6 wks, 10 wks, 4 mths, 6 mths, 12 mths: (none, mild, moderate, severe) Untreated: (0,2,3,1), (4,2,0,0), (5,1,0,0),		

					(5,1,0,0),(5,1,0,0), (6,0,0,0)		
		DMB N=6			DMB: (0,4,2,0), (4,2,0,0), (6,0,0,0), (5,1,0,0),(4,2,0,0) , (6,0,0,0)		
		Collagen type I N=6			Collagen type 1: (6,0,0,0), (4,2,0,0), (2,4,0,0), (5,1,0,0), (5,1,0,0) , (6,0,0,0)		
		OP-1 (2.5mg) with Collagen type I N=6			OP-1 on collagen type 1: (2,4,0,0), (2,4,0,0), (1,4,1,0), (3,2,1,0), (1,2,3,0), (3,2,1,0)		
Karrholm et al., 2006 UK (111) Miscellaneous 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 Median pain score (rng) 0, 2, 5 yrs rhBMP7/ALG 20 (0-44), 44 (30-44), 44 (40-44)	NR	
					Median Harris hip score (rng) 0, 2, 5 yrs rhBMP7/ALG 52 (18-83), 98 (72-100), 94 (68-99)		
		Cups ALG n=10			Cups Median pain score (rng) 0, 2, 5 yrs ALG 20 (10-44), 44 (30-44), 44 (40-44)		
					Median Harris hip score (rng) 0, 2, 5 yrs ALG 49 (11-93), 84 (72-98), 83 (76-100) (p=0.02 at 2 yrs)		
		Stems rhBMP7/ALG (1 g/pt) n=11			Stems Median pain score (rng) 0, 2, 5 yrs rhBMP7/ALG		

					20 (0-44), 44 (30-44), 44 (40-44)		
		Stems ALG n=30			Median Harris hip score (rng) 0, 2, 5 yrs rhBMP7/ALG 49 (18-82), 93 (68-100), 89 (75-99)		
					Stems Cups Median pain score (rng) 0, 2, 5 yrs ALG 20 (0-44), 44 (20-44), 44 (20-44)		
					Median Harris hip score (rng) 0, 2, 5 yrs ALG 49 (11-95), 85 (46-100), 85 (55-100)		
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)	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	NR	NR	Study reported only radiographic fusion results
		ICBG n=32			Iliac crest pain postharvest NR		