

TABLE E-1 Inclusion and Exclusion Criteria

Inclusion criteria

Degenerative disc disease accompanied by back pain of discogenic origin, with or without leg pain, with degeneration of the disc confirmed by patient history and radiographic studies

Degenerative disc disease present if one or more of the following was present:

Instability (defined as angulation of $\geq 5^\circ$ and/or translation of ≥ 4 mm, based on flexion-extension radiographs)

Osteophyte formation

Decreased disc height

Thickening of ligamentous tissue

Disc degeneration or herniation

Facet joint degeneration

Requires fusion of a single-level disc space from L1 to S1

Preoperative Oswestry Disability Index score of ≥ 30

No greater than Grade-1 spondylolisthesis utilizing the Meyerding Classification

Eighteen years of age or older at the time of surgery

Nonresponsive to nonoperative treatment (e.g., bed rest, physical therapy, medications, spinal injections, manipulation, and/or TENS [transcutaneous electrical nerve stimulation]) for a period of 6 months

If of child-bearing potential, non-pregnant, non-nursing, and agreed to use adequate contraception for 1 year following surgery

Willing and able to comply with the study plan and able to understand and sign the patient informed consent form

Exclusion criteria

Primary diagnosis of a spinal disorder other than degenerative disc disease with Grade-1 or less spondylolisthesis at the involved level

Previous lumbar spinal fusion procedure at the involved level

Requires spinal fusion at more than one lumbar level

Conditions that might have been associated with a diagnosis of osteoporosis, including:

Postmenopausal non-Black woman over 60 years of age and weighing less than 140 pounds

Postmenopausal woman who had sustained a nontraumatic hip, spine, or wrist fracture

Man over 70 years of age

Man over 60 years of age who had sustained a nontraumatic hip or spine fracture.

If the bone mineral density T-score was ≤ -3.5 , or ≤ -2.5 and the fracture was a vertebral crush fracture, the patient was excluded from the study

Previous diagnosis of osteopenia or osteomalacia

A condition that requires postoperative medications that interfere with fusion, such as steroids or prolonged use of nonsteroidal anti-inflammatory drugs, excluding routine perioperative nonsteroidal anti-inflammatory drugs. This does not include low-dose aspirin for prophylactic anticoagulation

Overt or active bacterial infection, either local or systemic

Presence of active cancer, or prior history of cancer (except for basal cell carcinoma of the skin)

Documented titanium allergy or intolerance

Mental incompetence

“Waddell Signs of Inorganic Behavior” score of ≥ 3

Prisoner

Alcohol and/or drug abuser currently undergoing treatment for alcohol and/or drug abuse

Received drugs that may interfere with bone metabolism (e.g., steroids or methotrexate) within two weeks prior to the planned date of spinal surgery

History of autoimmune disease (e.g., systemic lupus erythematosus or dermatomyositis)

History of exposure to injectable collagen or silicone implants

History of hypersensitivity to protein pharmaceuticals (monoclonal antibodies or gamma globulins) or collagen

Received treatment with an investigational therapy (device and/or pharmaceutical) within 28 days prior to implantation surgery, or such treatment is planned during the 16 weeks following rhBMP-2/CRM implantation

Received any previous exposure to any/all BMPs of either human or animal extraction

History of allergy to bovine products or a history of anaphylaxis

History of any endocrine or metabolic disorder known to affect osteogenesis

TABLE E-2 Preoperative Demographic and Clinical Characteristics*

	AMPLIFY (N = 239)	Control (N = 224)
Age† (yr)	53.2 ± 12.1 (20-81)	52.3 ± 13.3 (18-86)
Height† (m)	1.70 ± 0.09 (1.50-2.01)	1.69 ± 0.09 (1.47-1.98)
Weight† (kg)	84.9 ± 17.6 (47.2-164.2)	85.5 ± 18.7 (44.9-141.5)
Female sex	131 (54.8%)	129 (57.6%)
Race		
White	218 (91.2%)	203 (90.6%)
Black	11 (4.6%)	14 (6.3%)
Asian	3 (1.3%)	2 (0.9%)
Hispanic	4 (1.7%)	4 (1.8%)
Other	3 (1.3%)	1 (0.4%)
Marital status		
Single	15 (6.3%)	25 (11.2%)
Married	176 (73.9%)	155 (69.2%)
Divorced	29 (12.2%)	27 (12.1%)
Separated	4 (1.7%)	3 (1.3%)
Widowed	14 (5.9%)	14 (6.3%)
Education level		
Less than high school	24 (10.0%)	29 (13.1%)
High school	64 (26.8%)	73 (32.9%)
Greater than high school	151 (63.2%)	120 (54.1%)
Workers' Compensation case	27 (11.3%)	28 (12.5%)
Spinal litigation case	6 (2.5%)	15 (6.7%)
Tobacco use	63 (26.4%)	59 (26.3%)
Alcohol use	90 (37.7%)	78 (34.8%)
Preoperative work status		
Employed	83 (34.7%)	92 (41.1%)
Not employed	156 (65.3%)	132 (58.9%)
History of previous lumbar spine surgery	73 (30.5%)	62 (27.7%)
Diabetes	17 (7.1%)	27 (12.1%)
Liver disease	5 (2.1%)	0 (0.0%)
Total no. of Waddell signs		
0	219 (91.6%)	209 (93.3%)
1	15 (6.3%)	9 (4.0%)
2	5 (2.1%)	6 (2.7%)
Taking nonnarcotic medications	154 (64.7%)	140 (62.5%)
Taking weak narcotic medications	116 (48.5%)	116 (51.8%)
Taking strong narcotic medications	38 (16.0%)	41 (18.4%)
Taking muscle relaxants	55 (23.1%)	55 (24.7%)
Preop. Oswestry Disability Index†	49.9 ± 13.1 (28-86)	51.6 ± 13.3 (30-94)
Preop. SF-36v2 PCS†	27.8 ± 6.3 (15.3-48.7)	27.4 ± 6.7 (9.1-45.2)
Preop. SF-36v2 MCS†	43.9 ± 13.1 (13.3-68.5)	42.9 ± 12.3 (12.9- 69.3)
Preop. back pain score, scale 0-20†	15.6 ± 3.5 (0-20)	15.8 ± 3.6 (0-20)
Preop. leg pain score, scale 0-20†	14.0 ± 4.8 (0-20)	14.0 ± 5.3 (0-20)

*In certain categories, information was missing for 1 or 2 patients. SF-36v2 = Short Form-36 Survey version 2.0, PCS = Physical Component Summary, and MCS = Mental Component Summary. †The values are given as the mean and the standard deviation, with the range in parentheses.