

TABLE E-1 Demographic and Baseline Characteristics

	Autograft Group (N = 15)	rhBMP-2/Allograft Group (N = 15)
Age (yr)		
Mean and standard deviation	38 ± 15.4	36 ± 10.3
Range	18-71	18-51
Gender*		
Male	13 (87%)	14 (93%)
Female	2 (13%)	1 (7%)
Tobacco use within 1 month of implantation*		
No	11 (73%)	9 (60%)
Yes†	4 (27%)	6 (40%)
Pre-existing medical conditions*		
Diabetes	1 (7%)	3 (20%)
Cardiovascular disease	3 (20%)	1 (7%)
Mechanism of injury*		
Motor-vehicle versus pedestrian accident	4 (27%)	4 (27%)
Motor-vehicle/motorcycle accident	8 (53%)	9 (60%)
Other‡	0	2 (13%)
Gunshot wound	3 (20%)	0
Multiple trauma impacting walking ability*	9 (60%)	9 (60%)
Fracture type*		
Open	13 (87%)	14 (93%)
Closed	2 (13%)	1 (7%)
Fracture defect location*		
Proximal third	5 (33%)	3 (20%)
Middle third	7 (47%)	8 (53%)
Distal third	3 (23%)	4 (27%)
Gustilo-Anderson classification*§		
I or II	2 (15%)	1 (7%)
IIIA	8 (62%)	9 (64%)
IIIB	3 (23%)	4 (29%)
Method of coverage for type-IIIB fractures*#		
Myocutaneous flap/split-thickness skin graft	2 (67%)	3 (75%)
Free flap/split-thickness skin graft	1 (33%)	0
Primary closure	0	1 (25%)
OTA classification*		
Simple fracture (42-A)	0	1 (7%)
Wedge fracture (42-B)	8 (53%)	5 (33%)
Complex fracture (42-C)	7 (47%)	9 (60%)
Method of fracture fixation*		
Intramedullary nail	11 (73%)	10 (67%)
External fixation	4 (27%)	5 (33%)

\*The data are given as the number of patients, with the percentage in parentheses. †All were concurrent tobacco users. ‡Fall or industrial/farming machinery-related accident. §At the time of surgical exploration. The denominator is the number of open fractures. #The denominator is the number of type-IIIB fractures.

TABLE E-2 Bone Graft Implantation Summary

	Autograft Group (N = 15)	rhBMP-2/Allograft Group (N = 15)	Total (N = 30)
Time from injury to bone-grafting ( <i>wk</i> )			
Median	11	11	11
Range	6.3-12.4	7.1-12.3	6.3-12.4
Length of defect ( <i>cm</i> )			
Mean and standard deviation	4 ± 1.1	3 ± 1.2	4 ± 1.2
Range	2.5-7.0	1.0-5.0	1.0-7.0
Circumferential bone loss*			
50%	8 (53%)	10 (67%)	18 (60%)
75%	5 (33%)	2 (13%)	7 (23%)
100%	2 (13%)	3 (20%)	5 (17%)
Calculated fracture defect volume† ( <i>cc</i> )	9.4 ± 2.8	8.1 ± 5.0	8.8 ± 4.0
Bone graft implanted† ( <i>cc</i> )	39 ± 16.4	52 ± 12.8	46 ± 15.8
Tourniquet used*			
Yes	12 (80%)	13 (87%)	25 (83%)
No	3 (20%)	2 (13%)	5 (17%)
Grafting approach*			
Anteromedial	2 (13%)	2 (13%)	4 (13%)
Posterolateral	8 (53%)	9 (60%)	17 (57%)
Anterolateral	4 (27%)	3 (20%)	7 (23%)
Posteromedial	1 (7%)	1 (7%)	2 (7%)
Bone graft location‡			
Within fracture defect	14 (93%)	13 (87%)	27 (90%)
Along proximal margin	13 (87%)	11 (73%)	24 (80%)
Along distal margin	13 (87%)	11 (73%)	24 (80%)
Other§	0	2 (13%)	2 (7%)
Deliberate tibiofibular synostosis*			
Yes	6 (40%)	7 (47%)	13 (43%)
No	9 (60%)	8 (53%)	17 (57%)
Duration of anesthesia† ( <i>min</i> )	169 ± 49.3	150 ± 82.7	159 ± 67.6
Estimated blood loss during surgery† ( <i>mL</i> )	353 ± 284.4#	117 ± 100.3#	235 ± 241.5

\*The data are given as the number of patients, with the percentage in parentheses. †The data are given as the mean and the standard deviation. ‡The data reflect all categories that apply in each case; thus, the percentages do not add up to 100%. §The “Other” category includes “across posterior tibia and segmental fracture” and “posterior.” #p = 0.0073 (Student t test).

TABLE E-3 Bone-Graft Integration and Clinical Fracture-Healing

	Bone-Graft Integration			Clinical Healing	
	No. of Patients Evaluated	Partial Integration*	Complete Integration*	No. of Patients Evaluated	Clinical Healing*
12 Weeks					
Autograft	14	11 (79%)	3 (21%)	14	3 (21%)
rhBMP-2/allograft	14†	13 (93%)	0	14	1 (7%)
18 Weeks					
Autograft	12†	7 (58%)	4 (33%)	12	5 (42%)
rhBMP-2/allograft	15	12 (80%)	3 (20%)	15	7 (47%)
6 Months					
Autograft	12†	4 (33%)	7 (58%)	12	9 (75%)
rhBMP-2/allograft	15	7 (47%)	8 (53%)	15	9 (60%)
8 Months					
Autograft	11	2 (18%)	9 (82%)	11	10 (91%)
rhBMP-2/allograft	13	6 (46%)	7 (54%)	13	10 (77%)
10 Months					
Autograft	14	2 (14%)	12 (86%)	14	10 (71%)
rhBMP-2/allograft	13‡	5 (38%)	8 (62%)	14	11 (79%)
12 Months					
Autograft	10‡	2 (20%)	8 (80%)	11	10 (91%)
rhBMP-2/allograft	13	6 (46%)	7 (54%)	13	13 (100%)

\*The data are given as the number of patients, with the percentage in parentheses. †This value does not equal the total number of patients with partial integration plus the total number with complete integration because the radiographs for one patient were evaluated but deemed “uninterpretable.”

‡This value does not equal the number of patients evaluated for clinical healing because radiographs were not made for one patient who had been deemed to have healing at an earlier visit (last outcome carried forward).

TABLE E-4 Comparison of Assessment of Radiographic Union by Clinical Investigator and Independent Radiologist

	Clinical Investigators		Independent Radiologist	
	Number of Patients Evaluated	Number of Patients with Radiographic Union	Number of Patients Evaluated	Number of Patients with Radiographic Union
12 weeks				
Autograft	14	4 (29%)	12	2 (17%)
rhBMP-2/allograft	14	2 (14%)	13	1 (8%)
18 weeks				
Autograft	12	7 (58%)	12	6 (50%)
rhBMP-2/allograft	15	8 (53%)	15	2 (13%)
6 months				
Autograft	12	8 (67%)	10	6 (60%)
rhBMP-2/allograft	15	10 (67%)	14	4 (29%)
8 months				
Autograft	11	9 (82%)	10	6 (60%)
rhBMP-2/allograft	13	10 (77%)	12	6 (50%)
10 months				
Autograft	14	11 (79%)	12	10 (83%)
rhBMP-2/allograft	13	11 (85%)	12	8 (67%)
12 months				
Autograft	10	9 (90%)	9	7 (78%)
rhBMP-2/allograft	13	12 (92%)	12	9 (75%)