

TABLE E-1 Patient Demographics for the Gustilo Type-III Open Fracture Subgroup

| | Control Group ^a (n = 65) | rhBMP-2 Group ^b (n = 66) |
|----------------------|--|--|
| US : BESTT | 10 : 55 | 8 : 58 |
| Average Age (yrs) | 36.3 | 33.3 |
| Male : Female | 57 : 8 | 57 : 10 |
| Smokers ^c | 45% (26 of 55) | 46% (27 of 58) |
| Type IIIA Fractures | 48 | 41 |
| Type IIIB Fractures | 17 | 25 |

- a) There were a total of 71 patients enrolled in the control treatment protocol and who were classified with a Type III fracture. One patient had an amputation, two were lost to follow-up, one experienced a protocol violation, and two requested to be removed from the study after enrollment, leaving n = 65.
- b) There were a total of 74 patients enrolled in the 1.5 mg/mL rhBMP-2 treatment group and who were classified with a Type III fracture. Two patients did not receive an intramedullary nail for the definitive fixation, two did not receive the rhBMP-2 implant, one had an amputation, one rhBMP-2 implant was lost during a subsequent irrigation procedure, one experienced a protocol violation, and one patient died as the result of a cerebrovascular accident, leaving n = 66.
- c) Percentages on smoking are only for patients who identified themselves as smokers or non-smokers.

TABLE E-2 Intramedullary Nail Diameter for the Gustilo Type-III Open Fracture Subgroup*

| | Control group (n = 65) | RhBMP-2 group (n = 66) |
|-------------|---------------------------|---------------------------|
| 8 mm | 17% | 18% |
| 9 mm | 51% | 47% |
| 10 mm | 19% | 11% |
| 11 mm | 12% | 16% |
| 12 or 13 mm | 1% | 8% |

*The values are given as the percentage of patients from each group.

TABLE E-3 Percentage of Patients Who Had Reamed Intramedullary Nailing to Treat Open Tibial Fractures Based on Country/Region from the Combined Database (n = 510)

| | % of Patients |
|---------------------|---------------|
| Australia | 25 |
| Belgium/Netherlands | 41 |
| Canada | 77 |
| France | 71 |
| Germany | 10 |
| Israel | 37 |
| Finland/Norway | 10 |
| South Africa | 22 |
| United Kingdom | 86 |
| United States | 47 |

TABLE E-4 Patient Demographics for the Reamed Intramedullary Nailing Treatment Subgroup

| | Control group ^a (n = 48) | RhBMP-2 group ^b (n = 65) |
|----------------------|--|--|
| US : BESTT | 10 : 38 | 10 : 55 |
| Average Age (yrs) | 34.9 | 33.2 |
| Male : Female | 38 : 10 | 50 : 15 |
| Smokers ^c | 39.5% (15 of 38) | 42.3% (22 of 52) |
| Type I Fractures | 15 | 15 |
| Type II Fractures | 15 | 22 |
| Type IIIA Fractures | 13 | 20 |
| Type IIIB Fractures | 5 | 8 |

- a) There were a total of 49 patients enrolled in the control treatment protocol, but one patient was never seen in follow-up and was excluded for this analysis, leaving n = 48.
- b) There were a total of 69 patients enrolled in the 1.5 mg/mL rhBMP-2 treatment group who had reamed intramedullary nailing. In one patient, the implant was lost during wound irrigation on day 2, post-implantation, and 3 patients were implanted without rhBMP-2 in the collagen sponge. All four patients were excluded for this analysis, leaving n = 65.
- c) Percentages on smoking are only for patients who identified themselves as smokers or non-smokers.