

TABLE E-1 Study Entry Criteria

Inclusion Criteria

1. The patient signed the institutional review board-approved informed consent form.
2. A bone defect in the hindfoot or ankle required arthrodesis with use of open surgical technique with supplemental bone graft, requiring one of the following procedures: ankle joint arthrodesis (tibiotalar arthrodesis), subtalar arthrodesis, calcaneocuboid arthrodesis, talonavicular arthrodesis, triple arthrodesis (subtalar, talonavicular, and calcaneocuboid joints), and double arthrodesis (e.g., talonavicular and calcaneocuboid joints).
3. The arthrodesis site was able to be rigidly stabilized with no more than three screws across the arthrodesis site. Supplemental screws external to the arthrodesis site(s) were also allowed.
4. The patient was independent, could walk, and could comply with all postoperative assessments.
5. The patient was at least eighteen years of age and was considered to be skeletally mature.

Exclusion Criteria

1. The patient had undergone previous surgery of the proposed arthrodesis site.
2. The arthrodesis site required plate fixation, more than three screws, or more than 9 cc of graft material.
3. There was radiographic evidence of bone cysts, segmental defects, or growth plate fracture around the arthrodesis site that may negatively impact osseous fusion.
4. There were untreated malignant neoplasm(s) at the surgical site, or the patient was currently undergoing radiotherapy or chemotherapy.
5. The patient had a preexisting sensory impairment (e.g., diabetes with baseline sensory impairment) that limited the ability to perform objective functional measurements. Patients with diabetes who were not sensitive to the 5.07 monofilament (Semmes-Weinstein) were excluded.
6. The patient had a metabolic disorder such as renal osteodystrophy or hypercalcemia known to adversely affect the skeleton, other than primary osteoporosis or diabetes.
7. The patient chronically used medications known to affect the skeleton (e.g., glucocorticoid usage >10 mg per day). Nonsteroidal anti-inflammatory drug (NSAID) use was excluded during the first six weeks postoperatively.
8. The patient had a neuromuscular or musculoskeletal deficiency that limited the ability to perform objective functional measurements.
9. The patient was physically or mentally compromised (e.g., was currently being managed for a psychiatric disorder, senile dementia, Alzheimer disease, and so forth) to the extent that the investigator judged the patient to be unable or unlikely to remain compliant.
10. The patient had an allergy to yeast-derived products.
11. The patient had undergone an investigational therapy or an approved therapy for investigational use within thirty days of surgery or during the follow-up phase of this study.
12. The patient was a prisoner, was known to be or was suspected of being transient, or had a history of drug or alcohol abuse within the twelve months prior to screening for study entry.
13. The patient was pregnant or was intending to become pregnant during the study period. A urine pregnancy test was administered within twenty-one days of the surgical visit to any female patient unless she was postmenopausal, had been sterilized, or was practicing a medically accepted method of contraception.
14. The patient was deemed morbidly obese (body mass index [BMI], >45 kg/m²).