Case Series Summary

The following presents twelve foot and ankle procedures that were performed in conjunction with the Avitus® Bone Harvester. Harvest sites were chosen based on volumetric needs and patient factors on a case-by-case basis. The patient population (EXHIBIT 1) included seven females and four males, with an average age of 60 years old (51-79 years range). Patients had an average height of 68 in (63-74 in range) with an average weight of 193lbs (140-290 lbs range). One of the eleven patients required revision due to non-compliance, yielding twelve total procedures.

Methods

Five (5) calcaneus, seven (7) proximal tibias, and one (1) distal tibia were harvested. One patient had a knee-prosthesis preventing proximal tibia harvest and was harvested from both distal tibia and calcaneus. No structural backfill was used at any harvest site. Cancellous bone and bone marrow were harvested using the Avitus® Bone Harvester. Cortical holes were created using the Avitus® Pilot Hole Creator.

Results

The amount harvested was influenced by the volume required for the defect. Calcaneus harvests yielded an average of 11 CC’s (5-14 CC’s range) of cancellous bone and 3 CC’s (1-5 CC’s range) of bone marrow in 2.6 mins (1.5-3.3 min range) of operative time. Proximal tibia harvests yielded an average of 20 CC’s of cancellous bone (10-30 CC’s range) and 13 CC’s of bone marrow (5-25 CC’s range) in an average of 3.5 mins (1.5-4.3 mins range) of operative time. The distal tibia harvest yielded 15 CC’s of cancellous bone and 10 CC’s of bone marrow in 4.0 mins of operative time (EXHIBIT 2). All harvests had negligible blood loss (0-10 CC’s range). No pain at the harvest site was reported at the 8 week post-op follow up mark for all patients. No harvest site complications were reported. Significant amounts of bone substitutes and synthetics were replaced with the use of the Avitus® Bone Harvester. The Avitus® Bone Harvester produced easy-to-handle and packable cancellous bone graft with bone marrow aspirate (EXHIBIT 3).
**Conclusion**

The Avitus® Bone Harvester is fast and minimally invasive to my patients with minimal harvest site pain and complications. The device is safe and efficient and allows me to procure large volumes of autologous cancellous bone with additional marrow. This product enabled me to offset substantial bone substitute and synthetic costs with gold-standard autograft.

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