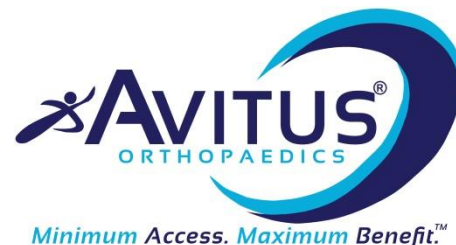


WHITE PAPER SERIES

A Case Series Review of the Avitus® Bone Harvester and Autologous Bone Harvesting for Foot & Ankle Applications



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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).

Patient Age (years)	Gender	Height (in)	Weight (lbs)
79	F	65	160
57	F	70	155
51	M	67	170
51	F	63	163
55	M	72	290
62	F	68	230
57	M	NA	NA
68	M	73	172
71	F	64	222
52	F	65	225
60	F	74	140

EXHIBIT 1 :: Tabulated patient population. Height and weight information not available for one patient (not included in average calculations).

Procedure	Harvest Site	Cancellous Volume (CC)	Bone Marrow Volume (CC)	Time of Harvest (mins)	Blood Loss (CC)
Triple Arthrodesis	CALC	12	5	1.5	0.0
Midfoot Fusion	CALC	14	3	3.3	0.0
Subtalar Open Fracture, Fusion*	CALC	12	2	2.5	0.0
Midfoot Fusion	CALC	12	1	3.0	0.0
Triple Arthrodesis	CALC/DT	20	15	7.0	0.0
Subtalar Arthrodesis	PT	30	5	4.0	0.0
Tibia Non-Union with bone graft	PT	10	20	1.5	10.0
Triple Arthrodesis	PT	15	20	4.0	0.0
Malunion repair with bone graft*	PT	30	5	3.5	0.0
Subtalar Arthrodesis	PT	30	5	3.0	0.0
Ankle Arthrodesis with X-fix	PT	12	25	4.3	10.0
Triple Arthrodesis	PT	15	10	4.0	0.0

EXHIBIT 2 :: Tabulated harvesting results. CALC = Calcaneus, DT = Distal Tibia, PT = Proximal Tibia. *Same patient. Patient's initial procedure resulted in a non-union due to non-compliance. Patient was revised using Avitus® proximal tibia autograft and fused successfully.

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A case series review of the Avitus® Bone Harvester
Autologous Bone Harvesting for Foot & Ankle Applications

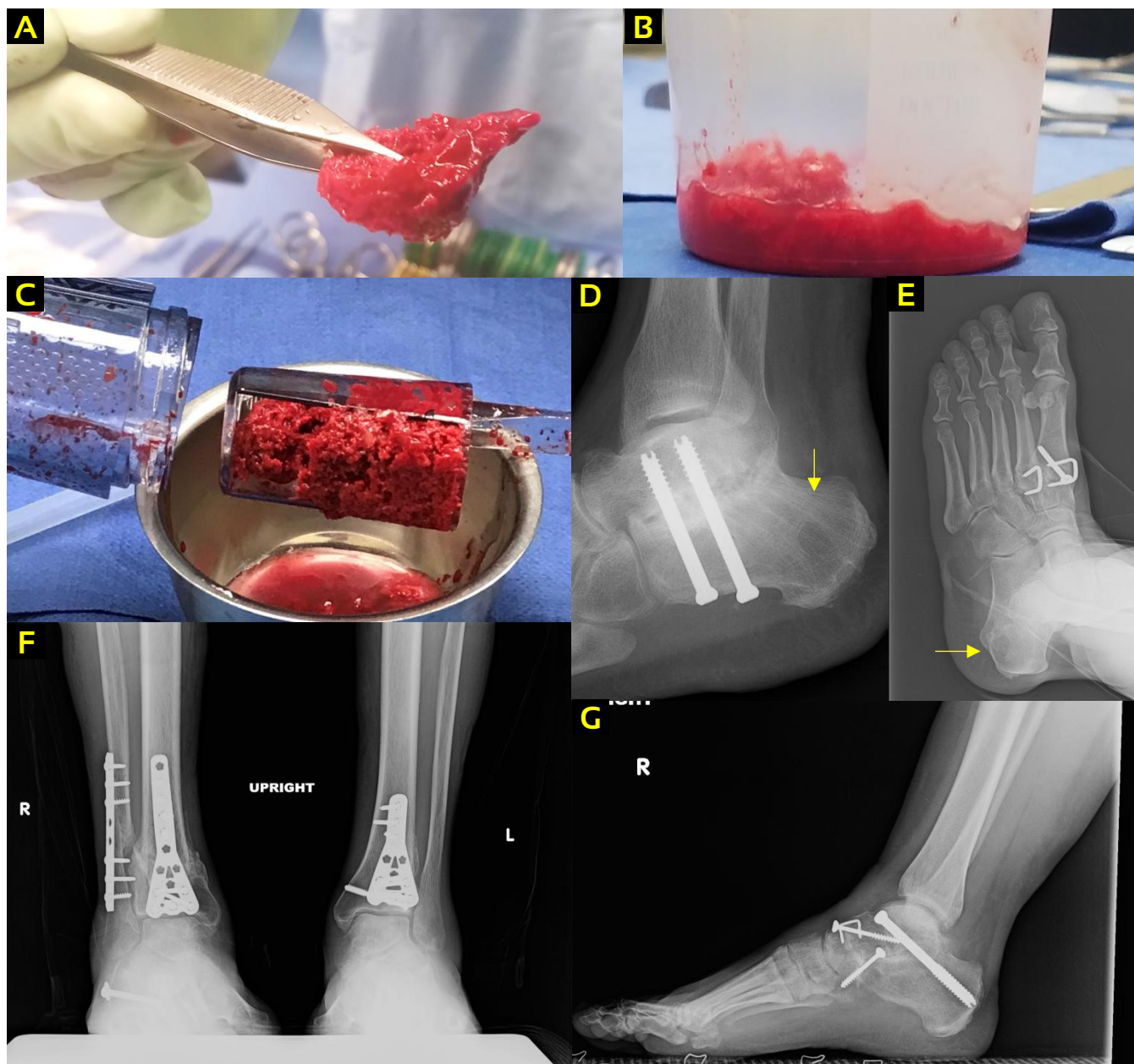


EXHIBIT 3 :: Select media from case series. A) A compacted chunk of Avitus-harvested autologous cancellous bone showing the packability and structure of graft collected with the Avitus® Bone Harvester. B) 12 CC's of autologous cancellous bone from a calcaneus harvest using the Avitus® Bone Harvester. C) 30 CC's of autologous cancellous bone and 5 CC's of bone marrow from a proximal tibia harvest using the Avitus® Bone Harvester. D) Subtalar joint fusion with calcaneus harvest site reconstitution. E) Midfoot fusion with calcaneus harvest site reconstitution. F) Malunion repair with Avitus® proximal tibia bone autograft. G) Triple arthrodesis fused with Avitus® proximal tibia bone autograft.

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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