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CASE STUDY:
A CLINICAL REVIEW OF AUTOGENOUS BONE GRAFTING FOR ORTHOPAEDICS AND THE AVITUS® BONE HARVESTER

BY
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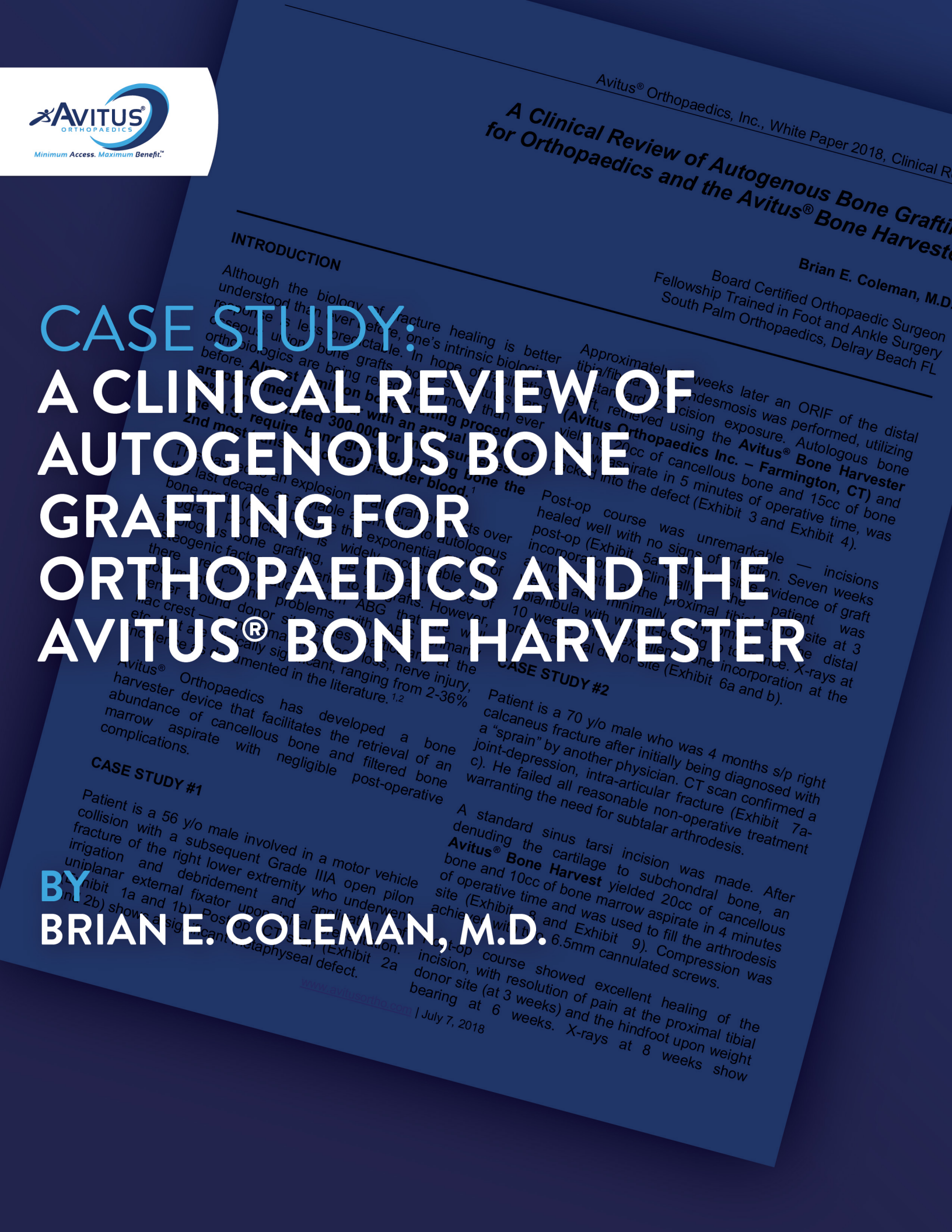

A Clinical Review of Autogenous Bone Grafting for Orthopaedics and the Avitus® Bone Harvester

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INTRODUCTION

Although the biology of fracture healing is better understood than ever before, one's intrinsic biological response is less predictable. In hope of facilitating osseous union, bone grafts, bone substitutes, and orthobiologics are being relied upon more than ever before. **Almost 1 million bone grafting procedures are performed each year with an annual growth of 13%. An estimated 300,000 or more surgeries in the U.S. require bone grafting, making bone the 2nd most transported material after blood.**[1]

This has led to an explosion of allograft products over the last decade as a viable alternative to autologous bone grafts (ABG). Despite this exponential growth of allograft products, it is widely acceptable that autologous bone grafting, due to its abundance of osteogenic factors, is superior to allografts. However, there are complications from ABG that are well documented. The problems with ABG primarily center around donor site issues, particularly at the iliac crest — pain, hematoma/blood loss, nerve injury, etc. that are clinically significant, ranging from 2-36% incidence as documented in the literature.[1,2]

Avitus® Orthopaedics has developed a bone harvester device that facilitates the retrieval of an abundance of cancellous bone and filtered bone marrow aspirate with negligible post-operative complications.

CASE STUDY #1

Patient is a 56 y/o male involved in a motor vehicle collision with a subsequent Grade IIIA open pilon fracture of the right lower extremity who underwent irrigation and debridement and application of uniplanar external fixator upon initial presentation. (Exhibit 1a and 1b). Post-op CT scan (Exhibit 2a and 2b) shows a significant metaphyseal defect.

Approximately 2 weeks later an ORIF of the distal tibia/fibula and syndesmosis was performed, utilizing a standard 2-incision exposure. Autologous bone graft, retrieved using the **Avitus® Bone Harvester (Avitus Orthopaedics Inc. – Farmington, CT)** and yielding 20cc of cancellous bone and 15cc of bone marrow aspirate in 5 minutes of operative time, was packed into the defect (Exhibit 3 and Exhibit 4).

Post-op course was unremarkable — incisions healed well with no signs of infection. Seven weeks post-op (Exhibit 5a-c) show visible evidence of graft incorporation. Clinically, the patient was asymptomatic at the proximal tibial donor site at 3 weeks and minimally symptomatic at the distal tibia/fibula with weight-bearing to tolerance. X-rays at 10 weeks show excellent bone incorporation at the proximal tibial donor site (Exhibit 6a and b).

CASE STUDY #2

Patient is a 70 y/o male who was 4 months s/p right calcaneus fracture after initially being diagnosed with a "sprain" by another physician. CT scan confirmed a joint-depression, intra-articular fracture (Exhibit 7a-c). He failed all reasonable non-operative treatment warranting the need for subtalar arthrodesis.

A standard sinus tarsi incision was made. After denuding the cartilage to subchondral bone, an **Avitus® Bone Harvest** yielded 20cc of cancellous bone and 10cc of bone marrow aspirate in 4 minutes of operative time and was used to fill the arthrodesis site (Exhibit 8 and Exhibit 9). Compression was achieved with two 6.5mm cannulated screws.

Post-op course showed excellent healing of the incision, with resolution of pain at the proximal tibial donor site (at 3 weeks) and the hindfoot upon weight bearing at 6 weeks. X-rays at 8 weeks show

satisfactory crossing of trabecular at the subtalar arthrodesis site (Exhibit 10).

SURGICAL TECHNIQUE — AVITUS BONE HARVESTER (Author's recommendation)

(1) Size of recipient site (defect, nonunion, or arthrodesis site) determines location of donor site. Most to least volume: distal femur/proximal tibia > distal tibia > calcaneus. **Proximal tibia by far most common donor site for foot and ankle procedures.**

(2) Optimal location in proximal tibia is 3 cm medial to the tibial crest just inferior to the metaphyseal flare. **Utilize C-arm fluoroscopy to localize the donor site entry point** (Exhibit 11).

(3) Make an incision 5mm larger than the selected Avitus® Pilot Hole Creator (1.5-2cm). Penetrate the cortex with the sharp anchor tip followed by 360 degree clockwise rotations until tip has been fully seated into the bone.

(4) Proper technique of the Avitus® Bone Harvester can be confirmed by an auditory **"scraping sound"** while executing curette-like scraping motions with the device while concurrently monitoring the amount extracted in the container.

(5) **Separate** the cancellous bone and the bone marrow aspirate by first pouring the bone marrow out the back-end of the harvester (Exhibit 12 and Exhibit 8).

(6) Backfill of the donor site is optional. If the surgeon chooses to, gel foam, cancellous chips, or a cortical plug can be considered.

(7) The bone marrow aspirate can be injected at the fusion site and/or at the incision site.

DISCUSSION

It is widely known that autologous bone graft (ABG) is the "gold standard" substrate vs. allograft bone graft due to its superior osteogenic, osteoinductive, and osteoconductive properties. Secondary factors such as cost and negligible immunogenic risk are also advantageous over allograft. [1,2]

Conceived in the 1970s but not available for clinical use until the late 1990s, the RIA (Reamer/ Irrigator/Aspirator—Synthes, Inc.) was the first device that harvested ABG from the intramedullary canal of the femur and tibia. Although a reasonable alternative to iliac crest bone graft issues, the RIA is fraught with its own problems. The literature reports complications such as alteration of the harvested graft substrate from the irrigation flow system, insertion site pain (hip abductors), femoral shaft fractures from eccentric reaming, and post-op blood loss requiring transfusion. [3]

The Avitus® Bone Harvester is an excellent device choice when considering ABG harvesting in foot and ankle procedures. The Harvester can yield over 40cc cancellous bone and 20cc of bone marrow aspirate from the proximal tibia. If smaller volumes of graft are required, the distal tibia and calcaneus donor sites can be considered. Clinically, post-operative pain at the donor site resolves in 2-4 weeks with no reportable complications from the procedure.

Product costs also play a major role in bone graft selection. The Musculoskeletal Transplant Foundation (MTF) manages the vast majority of the allografts on the market. The MTF reports cancellous chips ranging from $376-$396/30ml vials, femoral shaft cortical $1,530-$1,681, and BMP-2 (Infuse, Medtronic) $3,500-$4,900. Typically these products are packaged in 5, 10, 15, and 20ml packages inevitably leading to wasted material.

The cost of the Avitus Bone Harvester is substantially less than these autograft alternatives and significantly less than most allograft materials while producing graft with superior osteogenic properties. In addition, the surgeon can consider major or large bone graft (CPT—20902) **and** bone marrow (CPT—38220).

CONCLUSION

In conclusion, when analyzing bone grafting options, the Avitus Bone Harvester merits strong consideration due to the impressive volume of autologous bone graft and bone marrow aspirate, virtually no morbidity at the donor site, and cost savings from utilization of the device.

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BIBLIOGRAPHY

(1) Roberts, T, Rosenbaum, A. Bone grafts, bone substitutes, and orthobiologics. Osteogenesis 8:4, 114-124. Oct./Nov./Dec. 2012.
(2) Hatch, Daniel. Orthobullets—Bone Grafting/basic sciences, 1-9.
(3) Haubruck, P, Ober, J, Heller, Miska, M. Complications and risk management in the use of the RIA system. Plos/One, 1-10. April 26, 2018.

EXHIBITS

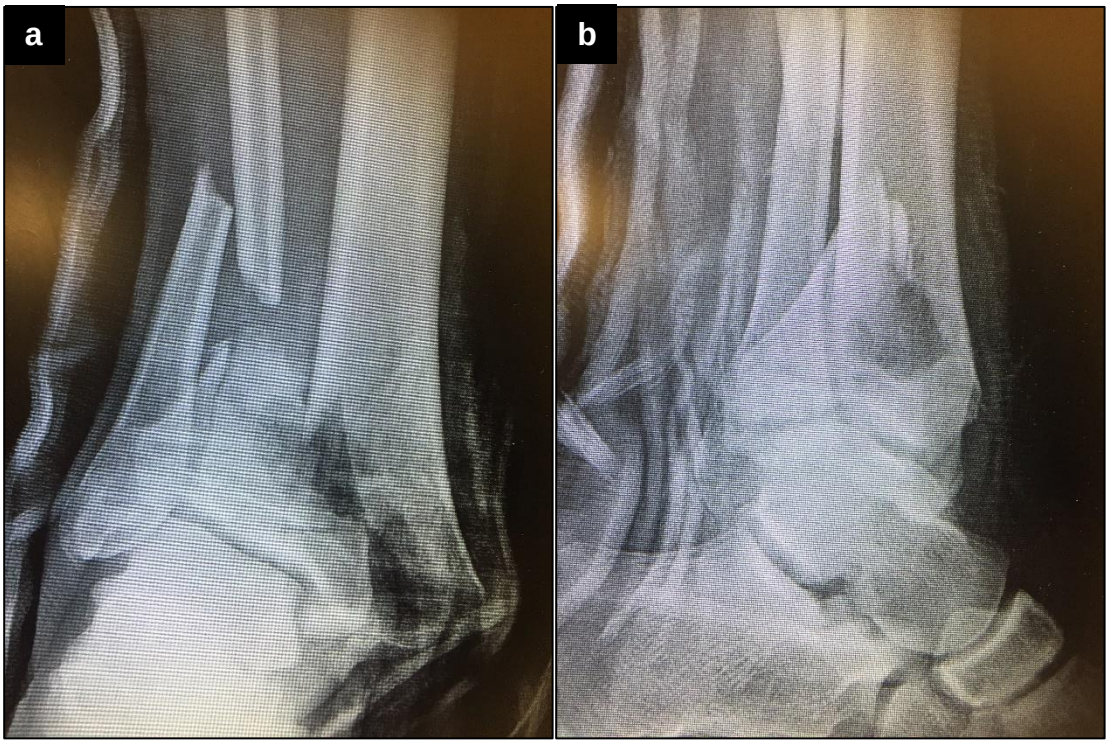

Exhibit 1 :: Initial presentation a) AP and b) Lateral radiographs of displaced pilon fracture

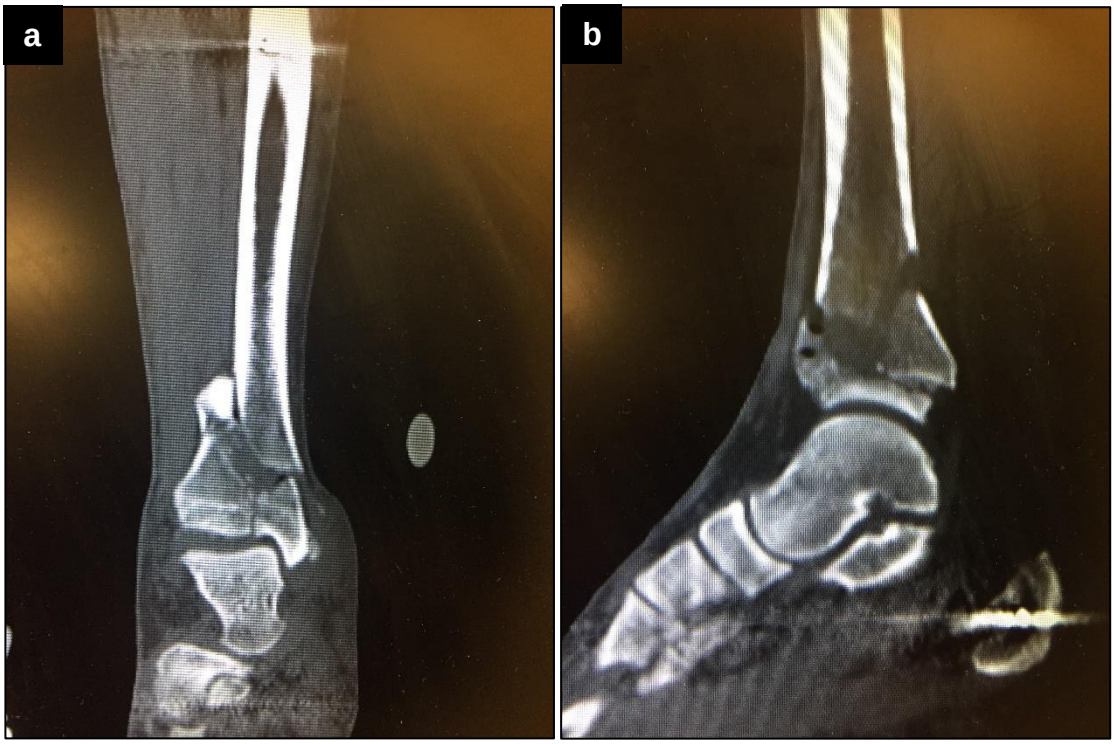

Exhibit 2 :: Post initial irrigation and debridement a) Coronal and b) Sagittal plane CT-scan of metaphyseal defect

Exhibit 3 :: 20cc of autologous cancellous bone and 15cc of bone marrow (blue cup) retrieved from the Avitus® Bone Harvester in 5 minutes of operative time

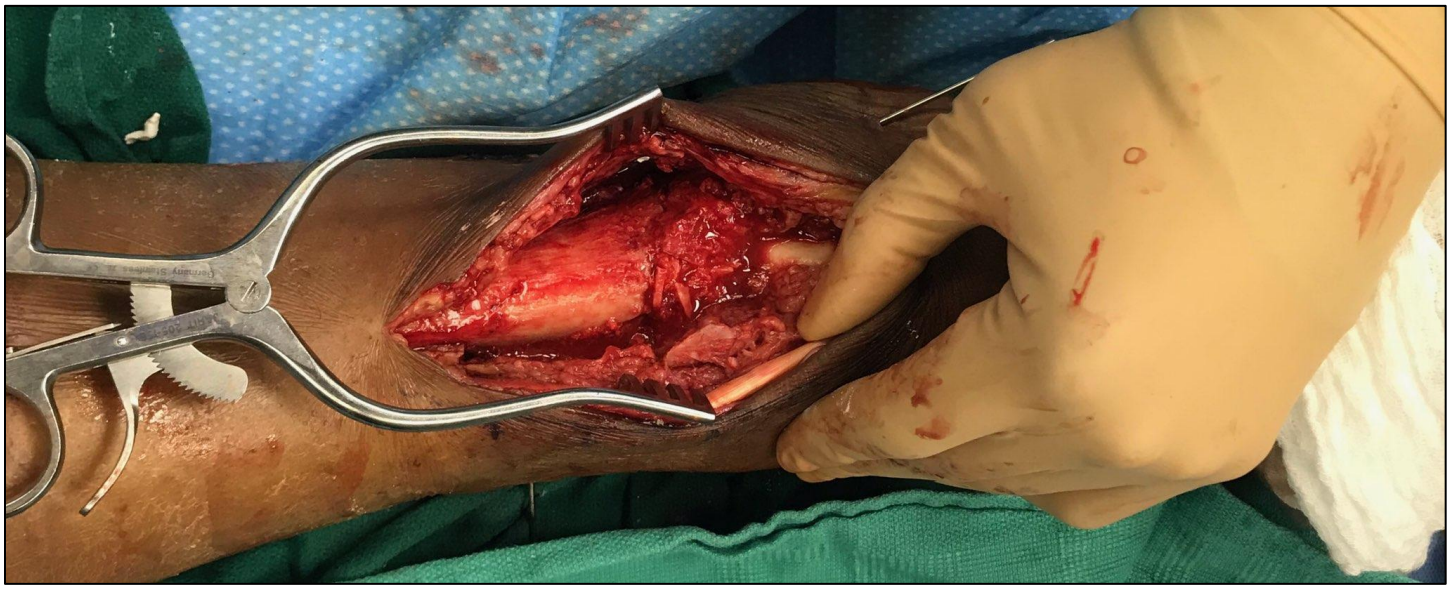

Exhibit 4 :: 20cc of autologous cancellous bone and 15cc of bone marrow retrieved from Avitus® Bone Harvester packed into the defect. The Avitus-harvested autologous bone graft had excellent handling characteristics, packability and structural stability

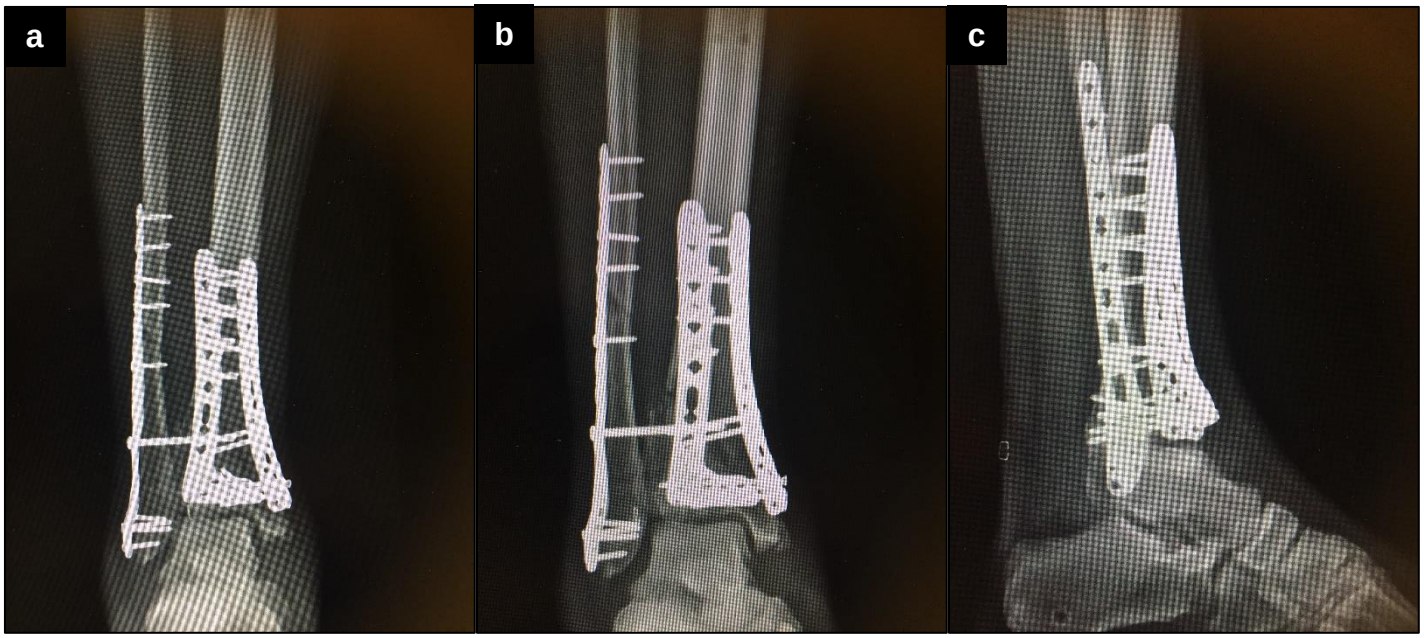

Exhibit 5 :: a-c) 7 week post-operative radiographs with visible evidence of bone graft incorporation

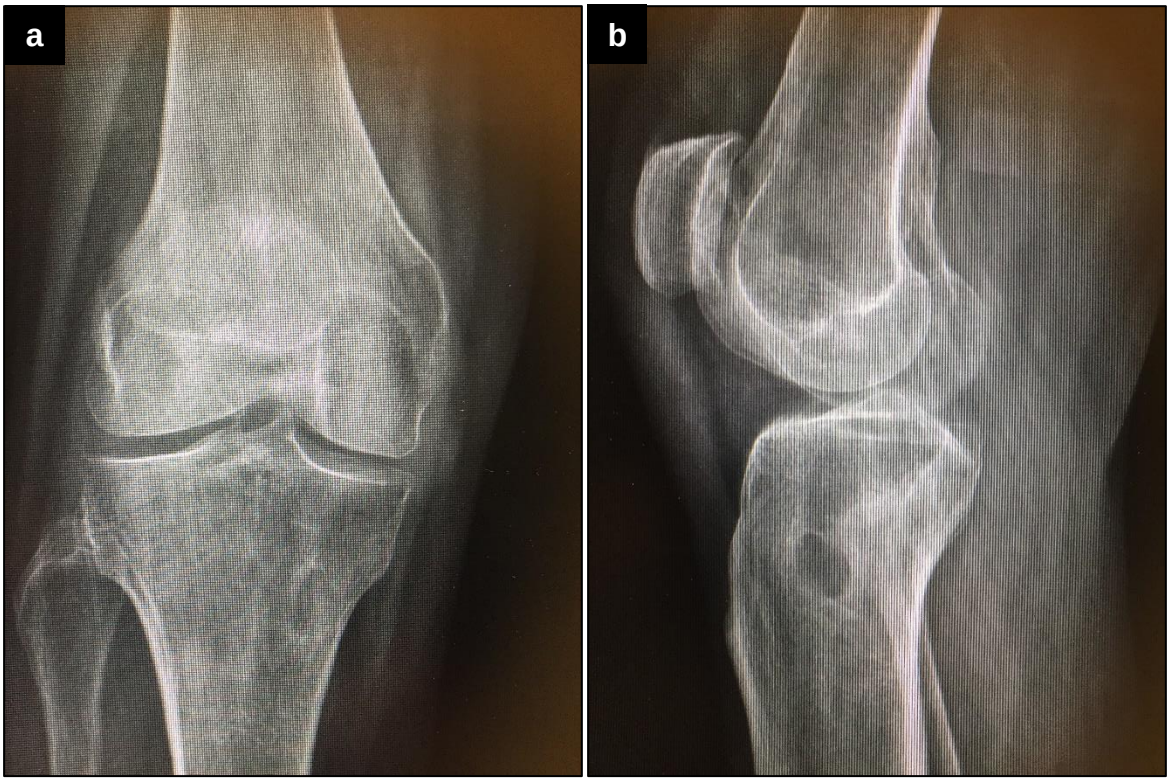

Exhibit 6 :: a) Coronal b) lateral radiographs at 10 weeks post-harvest show excellent bone incorporation at the proximal tibial donor site

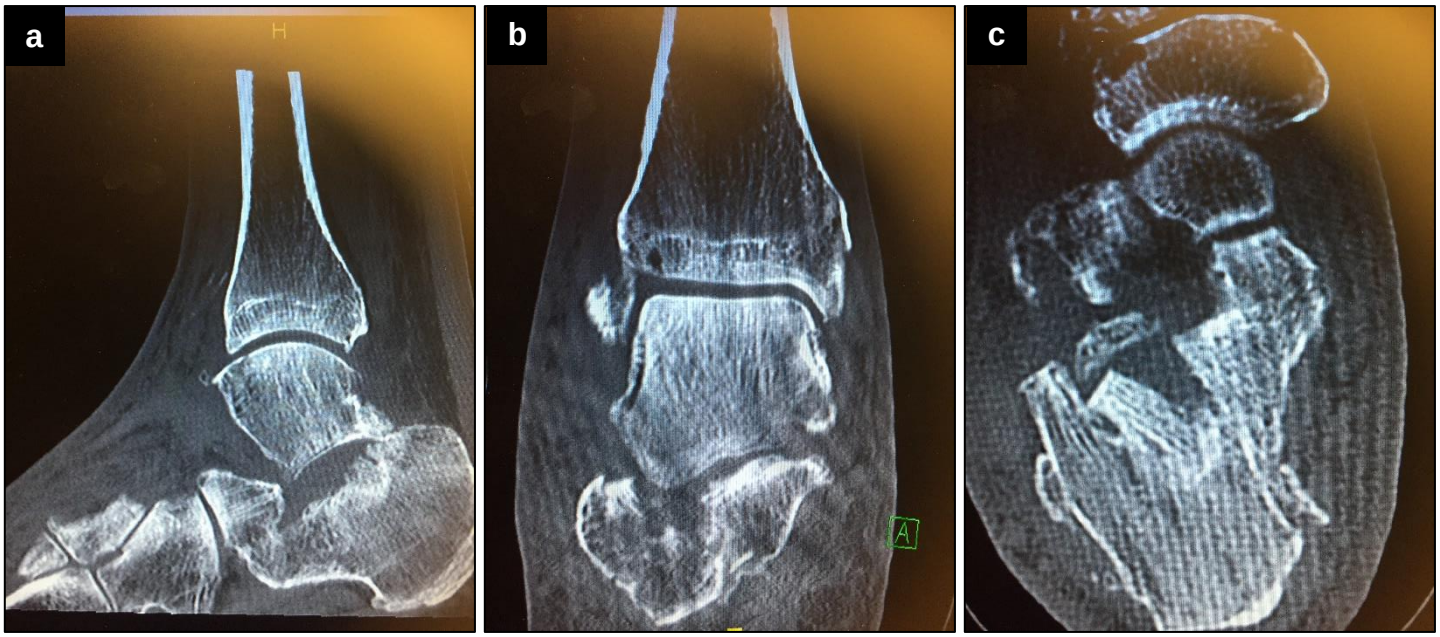

Exhibit 7 :: a-c) CT Scans showing joint depression and comminuted calcaneus fracture

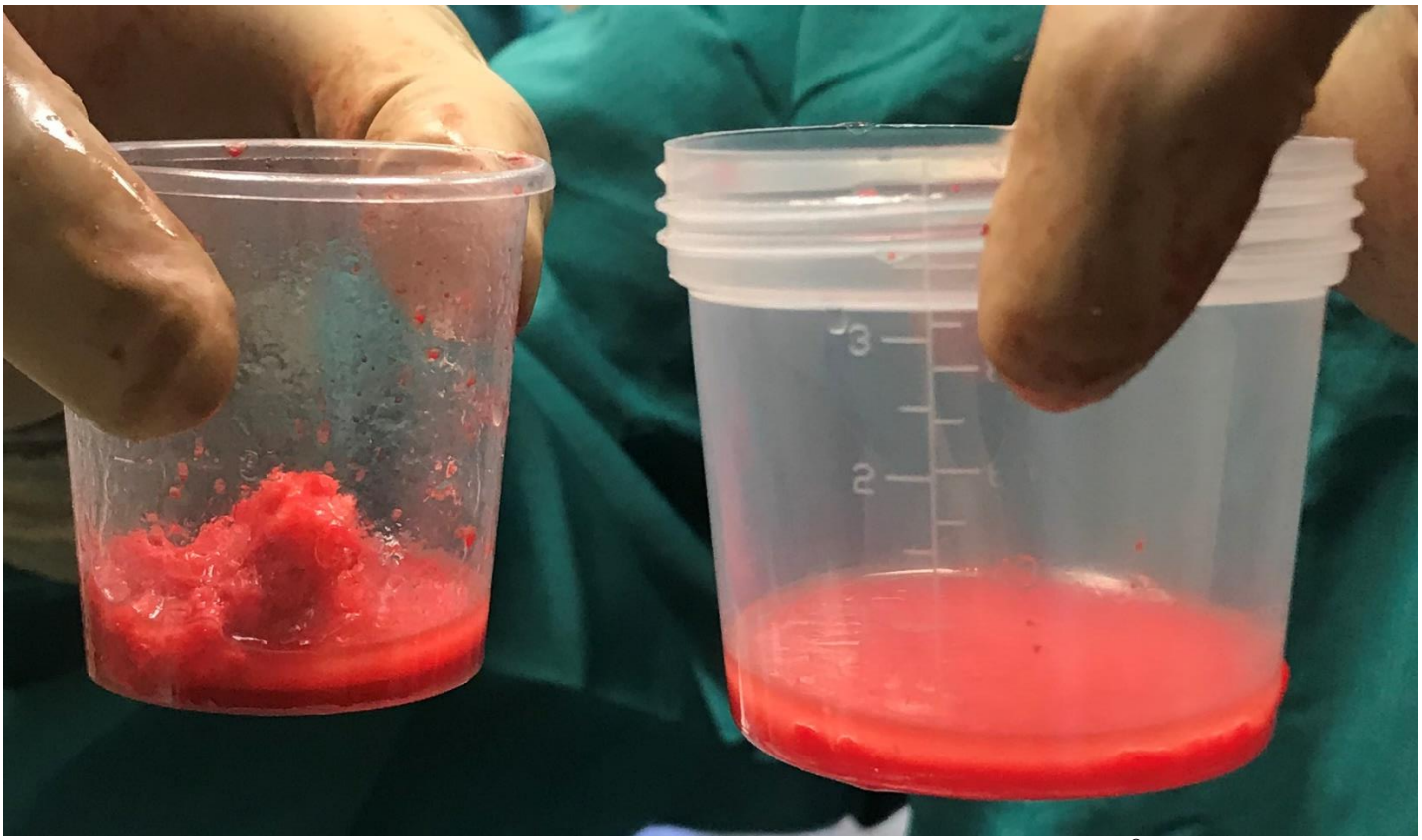

Exhibit 8 :: 20cc of autologous cancellous bone and 10cc of bone marrow collected with the Avitus® Bone Harvester in 4 minutes of operative time

Exhibit 9 :: Subtalar joint packed with Avitus® harvested autologous graft

Exhibit 10 :: Radiograph at 8 weeks shows satisfactory crossing of trabecular at the subtalar arthrodesis site

Exhibit 11 :: Optimal location in proximal tibia is 3 cm medial to the tibial crest just inferior to the metaphyseal flare. Utilize C-arm fluoroscopy to localize the donor site entry point (Author's recommendation)

Exhibit 12 :: Separation of the cancellous bone and the bone marrow aspirate by pouring the bone marrow out the back-end of the harvester