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CASE SERIES:
A RETROSPECTIVE REVIEW OF CLINICAL OUTCOMES USING THE AVITUS® BONE HARVESTER

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Case Series: A Retrospective Review of Clinical Outcomes Using the Avitus® Bone Harvester

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INTRODUCTION

In foot and ankle surgery, there are numerous procedures that indicate the use of a bone graft, including but not limited to non-union correction, fracture healing, delayed unions, arthrodesis, replacement of bone defect, and tumor repair. Although synthetic and allograft options do aid in healing of bone, autograft has continued to be the "gold standard" in bone regeneration.[1]

Wrotslavsky cited Cowan and Rajaee stating that patients and providers are steering away from autograft harvesting because of concerns of associated pain and morbidity at the donor site.[2,3,4] Wrotslavsky continues that synthetic options are usually inferior in most studies when compared to autograft options and the cost is much higher for allograft and synthetic grafts.[2,5,6]

With an aging population and associated co-morbidities such as type II diabetes and autoimmune disease on the rise,[7] there is a potential for increase in non-union risk factors. Furthermore, hospitals are constantly trying to decrease costs for surgical procedures. With autograft being a less expensive option than synthetics and allografts and with studies indicating improved results with autograft, it is imperative that physicians are willing to use autograft in supplementing surgical procedures. The purpose of this study is to evaluate the Avitus® Bone Harvester as a means to harvest distal tibia bone graft and determine if it is a clinically effective, simple, and cost-effective option with low complication rates.

PATIENTS AND METHOD

Fifteen patients underwent fifteen minimally invasive autograft bone harvests from the metaphysis of the distal tibia using the Avitus® Bone Harvester. The surgical procedures that indicated the need for autograft consisted of non-union repair, repair of severe osteochondral defect, charcot joint reconstruction, primary fusion for high risk patients, and trauma. **EXHIBIT 1** depicts demographics and procedures performed for all fifteen patients.

Surgical Technique: Attention is directed to the anteromedial face of the distal tibia approximately 4-6cm proximal to the ankle joint (also referred to as the flare of the distal tibia metaphysis). The location is verified under fluoroscopy to ensure that the ankle joint is not disturbed. A 2-3cm vertical incision is made, and blunt dissection is performed down to the periosteum. The periosteum is then cut along the same direction as the skin incision and is reflected back exposing the bone.

A 10.5mm circular cortical window is created using the Avitus® Pilot Hole Creator (**EXHIBIT 2)**. Any small boney fragments created during entry are carefully removed with a pick-up and set aside (alternatively, these fragments can be collected with the suction from the Avitus® Bone Harvester). The 8mm Avitus® Bone Harvester is then connected to suction and inserted into the harvest site (**EXHIBIT 3**). A series of scrapes and scoops are then executed by navigating the cutting element of the Avitus® Bone Harvester through the cancellous space inside the distal tibia. Occasionally, fluoroscopy images are taken to maintain a 1cm margin between the ankle joint during the harvest **(EXHIBIT 4).** Harvesting is performed for 2 to 5 minutes depending on how much volume is required for the index procedure. Once the desired amount of bone graft and bone marrow aspirate are obtained (which can range between 5 to 15cc of autogenous cancellous bone and 5 to 10cc of bone marrow aspirate), the contents from the inside of the handle of the device are removed (**EXHIBIT 5**). Depth markings on the device provide visual feedback in addition to the tactile feedback experienced throughout the harvesting process, aiding in a controlled and safe retrieval process. The site is then irrigated with sterile saline (**EXHIBIT 6**).

Optionally, demineralized bone matrix or bone chips can be used to backfill the harvest site. After backfilling the harvest site, the periosteum is closed using 3-0 Vicryl, followed by deep closure and skin closure.

Each patient was instructed to maintain a non-weight bearing status for four to eight weeks followed by ambulation in a walking boot for an additional two to six weeks. The weight bearing course was always dependent upon the primary surgery being performed and not the harvest procedure.

Each patient would follow up in the office at three days, two weeks, one month, and three months following the surgery. X-rays of the harvest site were taken at two weeks, one month, and three months out from surgery. Each patient was monitored for pain and any complications at the harvest site using x-ray and examination in addition to obtaining a visual analog scale (VAS) pain score. Evidence of radiographic fusion and pain-free ambulation were observed and recorded throughout the post-operative follow up.

RESULTS

EXHIBIT 7 details the results of each primary procedure performed. All patients who received a fusion showed radiographic fusion by 10 weeks. All fifteen patients observed pain-free ambulation by 13 weeks.

EXHIBIT 8 details the post-operative complications and VAS pain scores of the 15 harvest sites. Of the 15 autograft harvests performed at the distal tibia, 14/15 patients experienced no complications. One of the patients experienced saphenous neuritis at the harvest site due to scar tissue formation under the incision. She had mild discomfort persisting at one-month post-op, but by six weeks following the procedure the scar tissue had resolved, and the patient was pain free at the harvest site.

X-rays were taken of the harvest sites at two weeks, one month, and three months following the procedure to monitor the harvest sites post-operatively (**EXHIBIT 9**). The x-rays taken at the third month were to ensure that bone healing was evident at the harvest site. All of the 15 patients showed no evidence of fracture at the harvest site, and all 15 showed radiographic evidence of bone healing at the harvest site at the three-month mark. All of the patients were weight bearing by three months and none experienced any pain at that time.

The complication rate of the harvest procedure was 6.25% (the single complication went on to resolve six weeks following the procedure), with a 100% satisfaction rate at three months out. The average VAS score was 1.4 at three days post-op, 0.25 at two weeks post-op, 0.25 at one-month post-op and 0 at three month.

DISCUSSION

Through this retrospective study, we have concluded that the Avitus® Bone Harvester is a viable, repeatable, low risk technique for autograft and marrow retrieval in the distal tibia. The device requires a minimal incision in order to procure adequate bone graft and marrow aspirate for most foot and ankle surgical procedures and applications, providing valuable biology to the primary procedures at a fraction of the cost of synthetics.

Our results of a 6.25% complication rate is close to the results that Anderson et al. achieved in their study, in which a complication rate of 4% was observed in 522 distal tibia bone graft harvest procedures.[8] In every case, we saw bone bridging across the harvest site at three months. The circular harvest site window created by the Avitus® Pilot Hole Creator is a stable construct that can equally distribute force across its perimeter. In studies performed with circular and square sections placed under uniaxial compression, it was demonstrated that pressure around the circular section was more uniformly distributed than that around the square section, allowing the circular section to hold a higher ultimate load capacity.[9]

CONCLUSION

With a 12% non-union rate in foot and ankle arthrodesis, it is of vital importance that physicians have the knowledge and skills to correct the problem when it presents itself.[10] With autograft offering osteoconductive, osteoinductive, and osteogenic properties, it continues to be the gold standard bone graft option.[11] Utilizing the Avitus® Bone Harvester to obtain distal tibia bone autografts offers our practice a simple, time saving, cost reducing, and minimally invasive approach with minimal complications and significantly high volume output of both cancellous bone and bone marrow while aiding our patients to pain-free ambulation.

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PT #	Age	Sex	Patient Medical History	Procedure Performed
1	51	F	DM, HLD, Osteopenia	Metatarsal Non-union repair
2	49	F	None	Navicular Non-union repair
3	70	F	DM, Hyopthyroid, Interstitial Lung Disease	Metatarsal Non-union repair
4	37	M	None	Repair of OCD Lesion
5	57	M	HTN, Smoker	STJ Fusion
6	46	F	Smoker, Depression	Midfoot Fusion
7	62	F	HLD, GERD	STJ Non-union Repair
8	71	F	HTN, Osteoporosis, MS	Lapidus Fusion
9	79	M	HTN, BPH	Triple Arthrodesis
10	64	M	DM II, BPH	Midfoot Fusion – Charcot Reconstruction
11	32	M	None	Talo-navicular Non-union Repair
12	63	F	HTN	STJ Non-union Repair
13	52	F	Hypothyroid	Repair of OCD Lesion
14	64	M	None	Repair of OCD Lesion
15	66	M	HLD, DM II	Fibula Non-union Repair

EXHIBIT 1 :: Demographics of fifteen patients in this retrospective review.

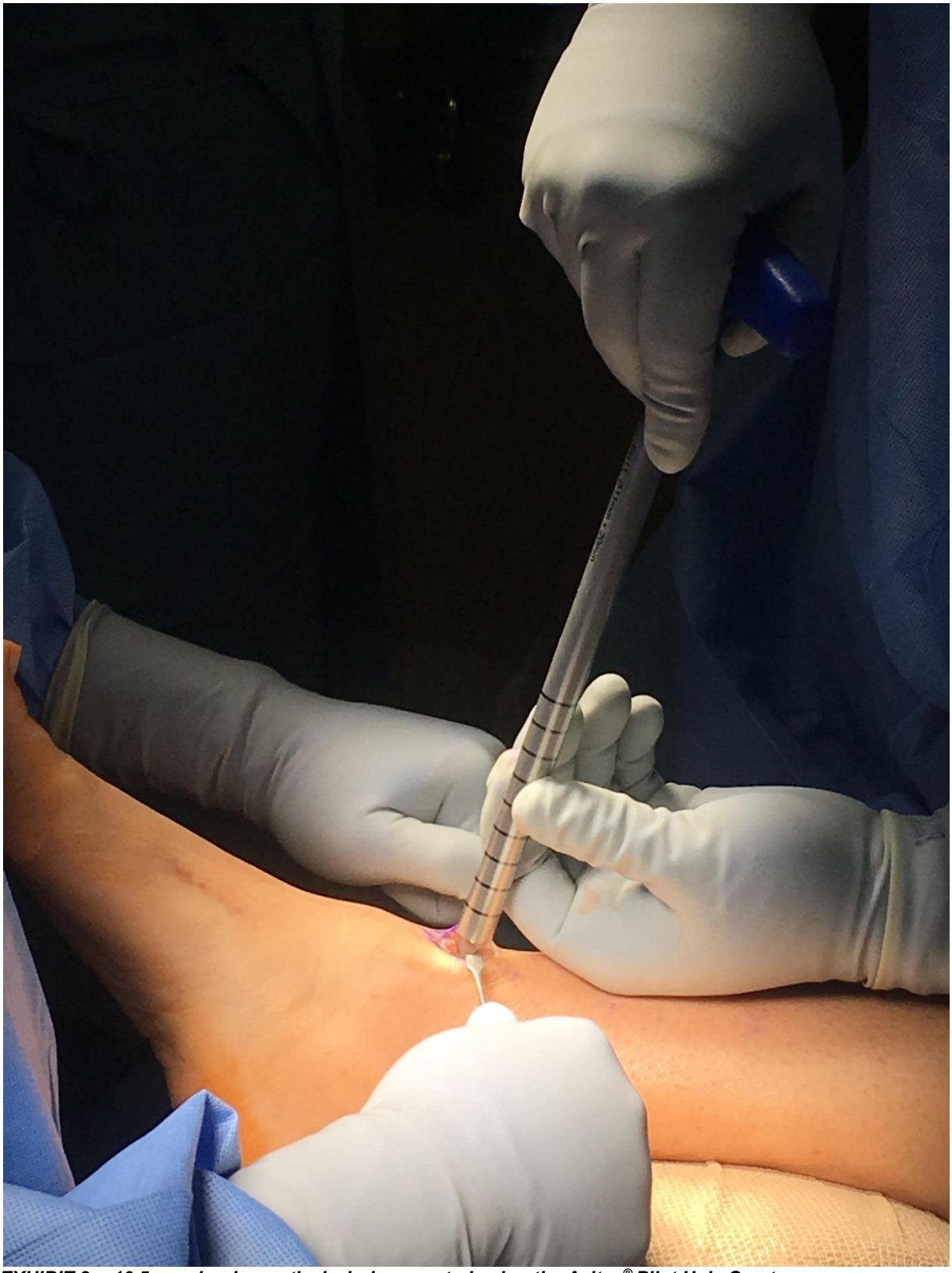

EXHIBIT 2 :: 10.5mm circular cortical window created using the Avitus® Pilot Hole Creator.

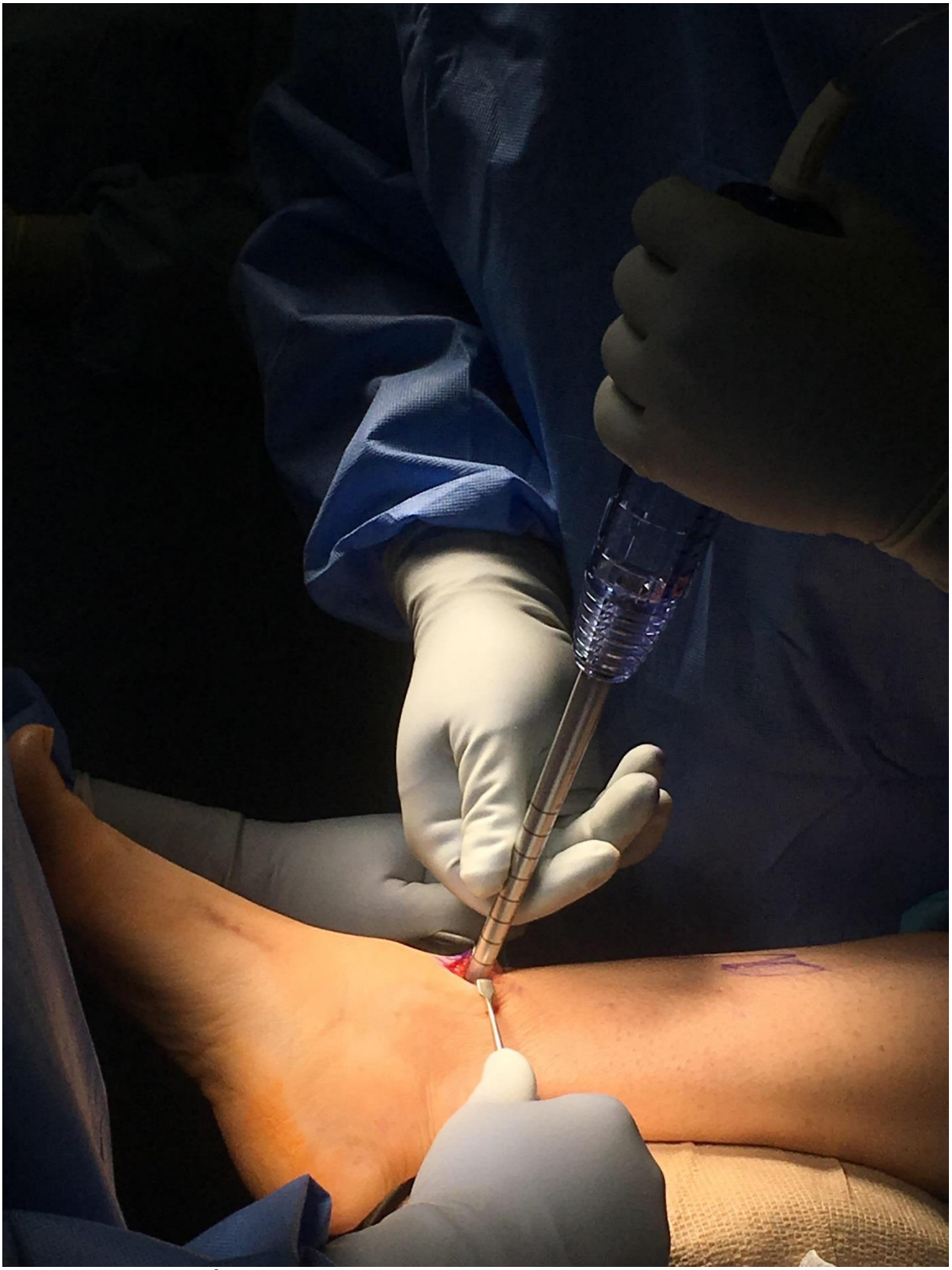

EXHIBIT 3 :: The Avitus® Bone Harvester inserted into the cortical entry of the distal tibia metaphysis.

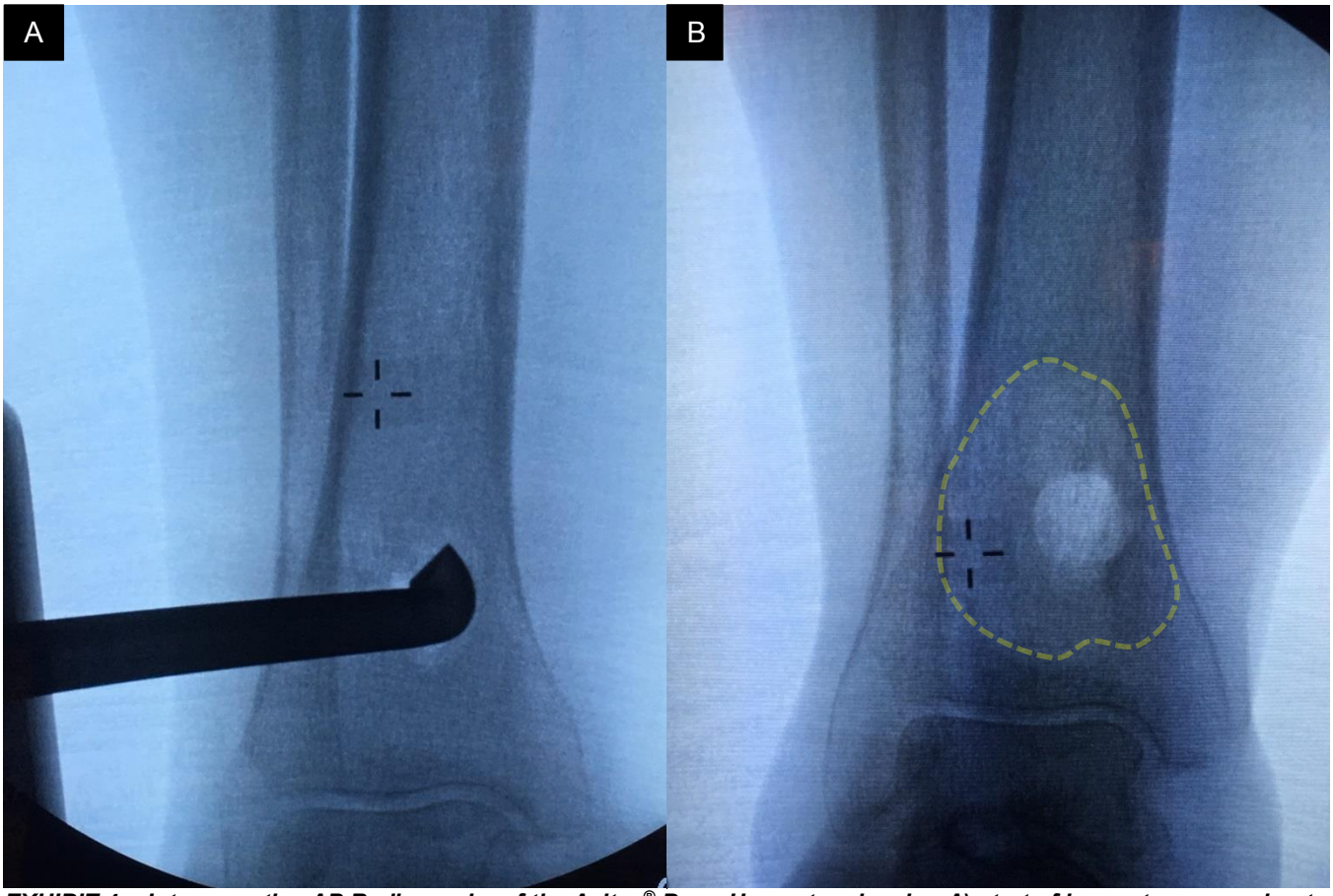

EXHIBIT 4 :: Intraoperative AP Radiographs of the Avitus® Bone Harvester showing A) start of harvest, progressing to B) complete harvest through the 10.5mm pilot hole.

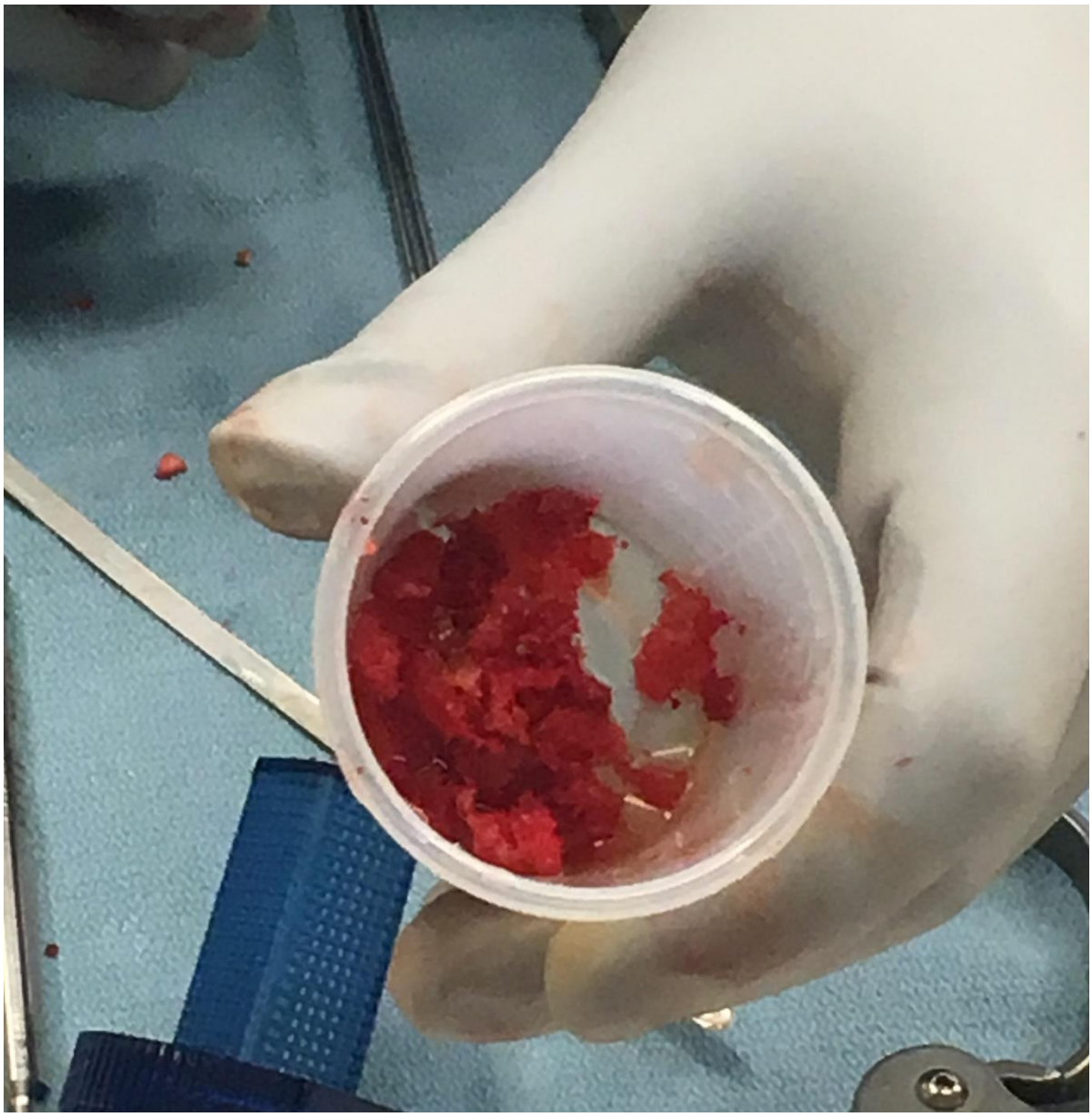

EXHIBIT 5 :: Once harvesting is complete, the harvested graft and marrow are emptied from the handle of the Avitus® Bone Harvester. Pictured here is 15cc of cancellous bone retrieved from the device.

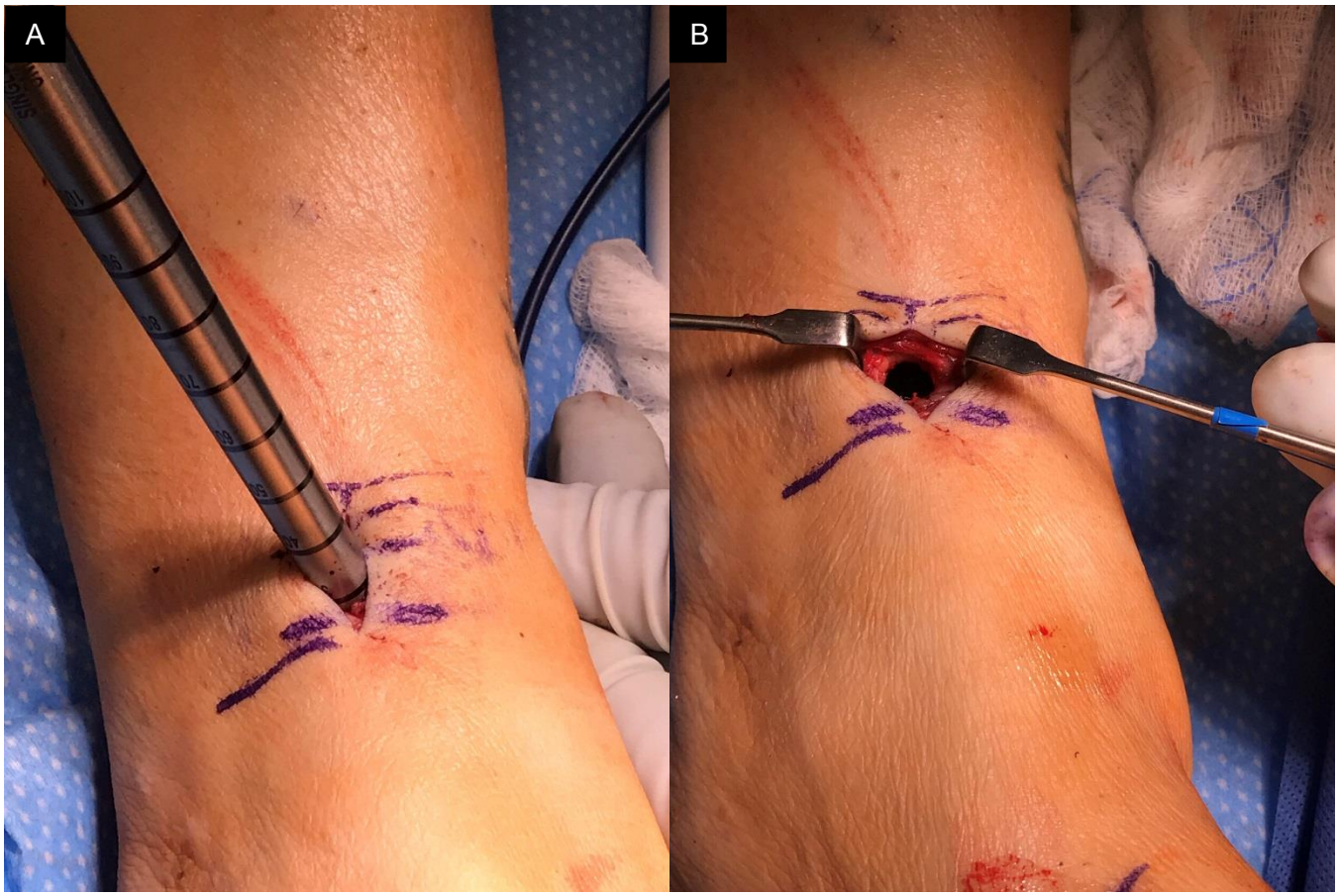

EXHIBIT 6 :: A) Depth markings on the device provide feedback in addition to tactile feedback of the cutting element of the Avitus® Bone Harvester. B) Sterile saline is used to flush the harvest site out post-harvest.

PT #	Procedure	Time to Radiographic Fusion	Time to Pain-Free Ambulation
1	Metatarsal Non-union repair	6 Weeks	9 Weeks
2	Navicular Non-union repair	4 Weeks	7 Weeks
3	Metatarsal Non-union repair	8 Weeks	8 Weeks
4	Repair of OCD Lesion	N/A	8 Weeks
5	STJ Fusion	6 Weeks	9 Weeks
6	Midfoot Fusion	8 Weeks	10 Weeks
7	STJ Non-union Repair	8 Weeks	13 Weeks
8	Lapidus	4 Weeks	7 Weeks
9	Triple Arthrodesis	8 Weeks	11 Weeks
10	Midfoot Fusion - Charcot Reconstruction	8 Weeks	12 Weeks
11	Talo-navicular Non-union repair	8 Weeks	8 Weeks
12	STJ Non-union Repair	10 Weeks	10 Weeks
13	Repair of OCD Lesion	N/A	8 Weeks
14	Repair of OCD Lesion	N/A	8 Weeks
15	Fibula Non-union repair	6 Weeks	10 Weeks

EXHIBIT 7 :: Table detailing a) the time points at which radiographic fusion was observed at the primary surgery site, and b) time at which patient returned to pain-free ambulation. Fusion was achieved for all patients who underwent a fusion procedure. All patients returned to pain-free ambulation.

PT #	Harvest Site Complication	VAS pain score at harvest site 3 day post-op	VAS pain score at harvest site 2 week post-op	VAS pain score at harvest site 4 week post-op	VAS pain score at harvest site 12 week post-op
1	Saphenous Neuritis	4	1	1	0
2	None	2	1	0	0
3	None	0	0	0	0
4	None	1	0	0	0
5	None	3	0	0	0
6	None	2	0	0	0
7	None	1	0	0	0
8	None	0	0	0	0
9	None	1	0	0	0
10	None	0	0	0	0
11	None	2	1	0	0
12	None	1	0	0	0
13	None	2	1	0	0
14	None	2	0	0	0
15	None	0	0	0	0
AVERAGE	-	1.4	0.25	0.06	0

EXHIBIT 8 :: Harvest site complication and VAS pain scores at 3 day, 2 week, 4 week, and 12 week post-op. One complication was observed across 15 harvests due to scarring at the harvest incision site.

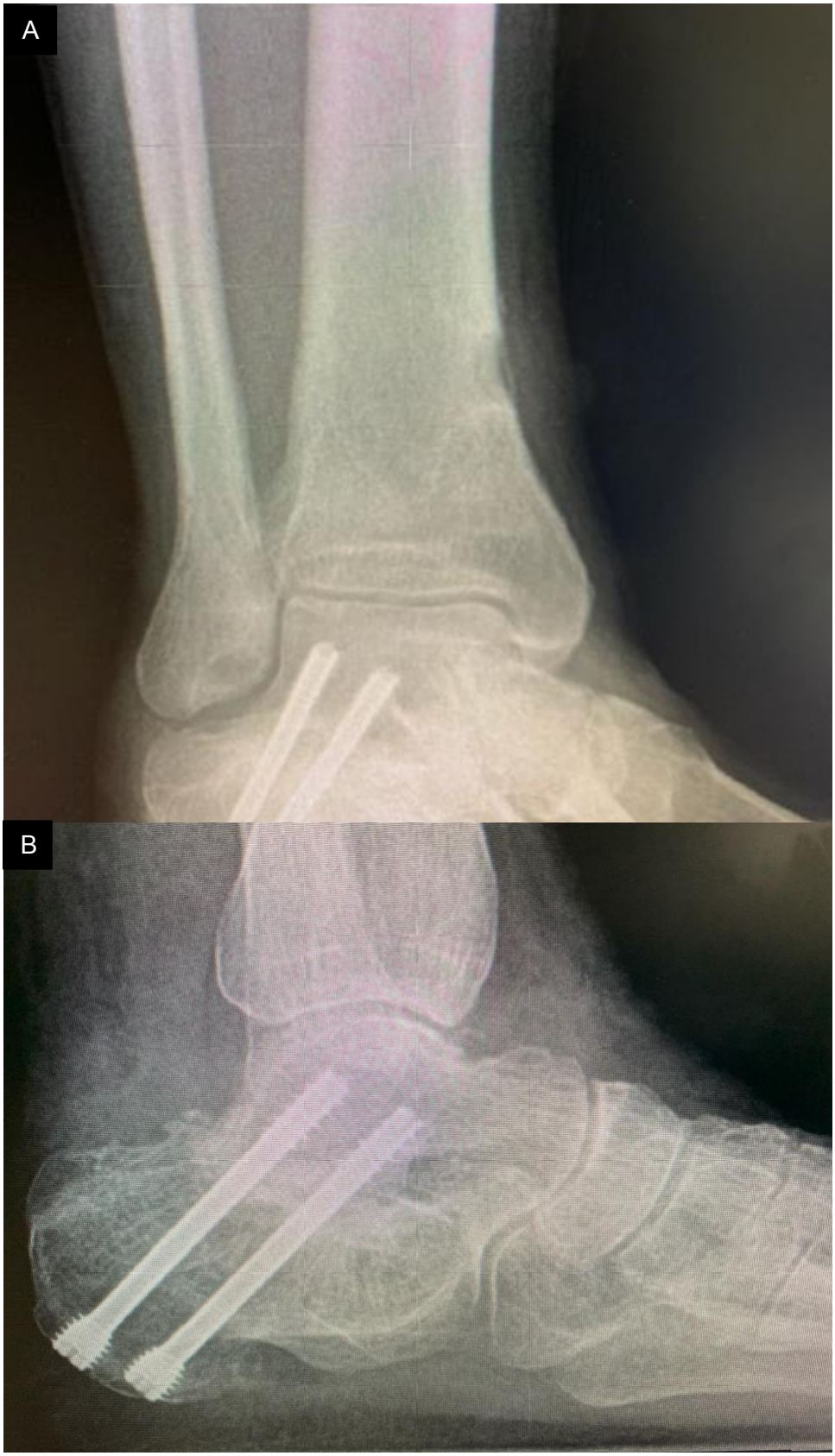

EXHIBIT 9 :: A) 12 week post-operative AP radiograph showing bone harvest site reincorporation B) 12 week lateral radiograph showing arthrodesis at the fusion site