Initial Results of the InCore Lapidus: Two Surgeons and Their Initial 12 Month Experience

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ABSTRACT

INTRODUCTION: Hallux valgus is a clinical entity associated with pain and deformity of the great toe. There are more than 250 surgical procedures reported to address this deformity. The rationale behind each operation often depends on the training of the surgeon, but more importantly perhaps the philosophy of the surgeon as to what constitutes the deformity. The condition is most commonly associated with deviation of the first metatarsal into varus, with the hallux drifting into valgus.

METHODS: This was a retrospective review of two surgeons' cases, demonstrating each surgeon's outcomes using the InCore Lapidus system over their first 12-month period of adopting the system. Each surgeon performed a chart review, and reviewed both pre and post-operative radiographs, as well.

DISCUSSION: The modified Lapidus arthrodesis has been a well-established technique for the surgical correction of hallux abducto valgus deformity. The procedure has been utilized for the treatment of severe and recurrent bunion deformity, hypermobile first ray, and insufficiency of the first ray. The modified Lapidus arthrodesis has gained recent popularity in the literature. Despite the effective reduction of the intermetatarsal angle and bunion deformity, the procedure can be technically challenging as well as associated with some disadvantages.

CONCLUSION: The InCore Lapidus fixation system demonstrates similar correction radiographically as other fixation constructs previously discussed throughout the literature. Additionally, union rates and time to weightbearing and time to regular shoe gear are very similar to the previously reported literature. Distinct advantages to the system such as allowing surgeon preference in joint preparation, visualization, and assistance with deformity reduction make it a viable fixation alternative to crossing screws or locking plates for Lapidus arthrodesis.

INTRODUCTION

Hallux valgus is a clinical entity associated with pain and deformity of the great toe. There are more than 250 surgical procedures reported to address this deformity. The rationale behind each operation often depends on the training of the surgeon, but more importantly perhaps the philosophy of the surgeon as to what constitutes the deformity. The condition is most commonly associated with deviation of the first metatarsal into varus, with the hallux drifting into valgus. There are many clinical entities and painful conditions that coexist with hallux valgus including associated pain in the lesser metatarsophalangeal joints (metatarsalgia) and lesser toe deformities such as hammertoes and claw toes. In advanced stages, pain may extend to the midfoot or hindfoot, as midfoot arthritis and hindfoot deformity develop.

Shoe wear eventually becomes difficult due to pain over the medial eminence associated with widening of the forefoot, which can be exacerbated by associated lesser toe deformities. Treatment options for hallux valgus begin with nonoperative measures, including extra width comfort shoes, soft upper lasts, orthotics, corticosteroid injections and anti-inflammatory medication. When nonoperative measures fail to alleviate symptoms, surgical treatment is an option.

The surgical options for hallux valgus are numerous and varied. These procedures range from distal metatarsal osteotomies for mild to moderate and occasional severe deformities, metatarsal shaft osteotomies, proximal osteotomies, and proximal fusions involving the first tarsometatarsal joint. Popularized by Paul Lapidus, the first tarsometatarsal fusion is commonly advocated for more severe deformities and revision procedures. In addition, the first tarsometatarsal arthrodesis is utilized for deformities associated with first ray instability, hypermobility or elevation, as is seen with forefoot varus. The frequency of proximal joint arthrodesis has increased over the past twenty years, as fixation options improve, surgeon experience grows, and the frequency of more complicated deformities increase with the aging and growing population.

A novel device was designed to assist the surgeon to stabilize the correction of the metatarsal during reduction, provide compression across the joint, and provide rigid fixation. In addition, the device is internal to the bone, which minimizes the need for hardware removal. Based on the results outlined in this study, patients were able to experience weightbearing at an average time of 25.1 days post-op.

The purpose of this study is to investigate early outcomes of patients undergoing first TMT fusion (Lapidus arthrodesis) using the InCore Lapidus device. Secondary outcomes include radiographic correction of deformity, complication rates, and recurrent surgeries.

METHODS

This was a retrospective review of two surgeons' cases, demonstrating each surgeon's outcomes using the InCore Lapidus system over their first 12-month period of adopting the system. Each surgeon performed a chart review, and reviewed both pre and post-operative radiographs, as well. Data points obtained include: Age, sex, laterality, BMI, smoking history, pre and post-operative intramedullary (IM) angles, pre and post-operative tibial sesamoid positions, and pre and post-operative hallux abductus angles. Additionally, the charts were reviewed for days to weightbearing in a boot and days to return to shoe gear. Finally, each chart was reviewed for complications, concurrent surgeries, and revisional surgeries.

Surgical Technique

Patients were typically placed in the supine position under general or regional anesthesia. A 2cm dorsomedial incision was created over the 1st MTPJ and the medial eminence was resected using a sagittal saw. A lateral capsulotomy and release was completed through the MTP joint space.

Attention was then directed toward the dorsal 1st MCJ where a 6-7cm incision was placed over the medial cuneiform extending down along the base of the first metatarsal. Subcutaneous dissection was carried down to the capsular structures and the EHL tendon was retracted laterally. Capsular dissection was carried out at the metatarsocuneiform joint (MCJ) and along the dorsal aspect of the medial cuneiform. A small osteotome was utilized to free up a dorsal and distal portion of the intercuneiform joint, taking care not to be overzealous in releasing the intercuneiform space. A larger osteotome was also utilized to mobilize and free up the plantar soft tissues of the 1st MCJ.

The post drill guide from the InCore Lapidus System was then placed dorsally with the large paddle between the medial cuneiform and the first metatarsal base and the small lateral paddle in the intercuneiform space. The post drill guide was aligned down the long axis of the first metatarsal with the pin hole oriented slightly dorsolateral to plantar medial. A 2mm pin was then placed in the medial cuneiform. Fluoroscopy confirmed placement of the pin parallel to the MCJ joint line. The pin placement was noted to be slightly lateral and proximal in the cuneiform. The post drill guide was removed.

The reamer was then placed over the 2mm guide pin and reamed down to the hard stop. The reamer and the guide pin were then removed. The cancellous bone from reaming as well as from the flutes of the reamer were placed in a specimen cup for augmentation of the fusion site later. The post and targeting guide assembly were then inserted into the reamed medial cuneiform. The post was fully seated below the bone surface. The compression-distraction "foot" was placed within the incision and along the medial aspect of the first metatarsal shaft. Frontal plane correction was then obtained by placing a 2mm pin dorsally in the base of the first metatarsal and using the pin as a joystick to rotate the metatarsal. Holding that frontal plane correction, two 2mm pins were placed through the compression distraction fixture. The

T10 screwdriver was then used to distract the MCJ by opening the compression distraction fixture.

Joint preparation was achieved with a sagittal saw on the cuneiform. A laterally based wedge off the cuneiform was resected taking care to minimize shortening. The base of the 1st metatarsal was prepared using curettage of the cartilage, fenestration of the subchondral bone using a 1.5mm drill bit and a small osteotome for fish scaling. The compression-distraction device was then returned to the "start" position. The cancellous bone harvested during the post reaming was inserted into the fusion site.

A point-to-point periarticular reduction forcep was used to close down the IM-angle correction. A 2mm pin was placed just proximal to the post in the targeting jig to prevent rotation around the post and loss of transverse plane correction.

After appropriate transverse IM correction was achieved, the T10 driver was used to compress across the joint using the compression distraction device. Care was taken to make sure the base of the first metatarsal did not migrate plantarward as the compression was achieved. The drill bushing was placed in the medial targeting guide hole and the 3.6mm drill bit was passed through the drill bushing and down to the step stop on the bit. The drill and bushing were then removed and the depth probe was placed flush to the bone through the guide. Care was taken not to over tighten or advance the screw beyond the obvious hard stop as the screw engaged the threaded post.

All 2mm pins and the targeting guide were removed. A post screw or end cap was placed in the post dorsally to prevent boney or soft tissue ingrowth. Layered closured was achieved. Intraoperative fluoroscopy confirmed proper correction, placement of the post and screws, and proper locking of the distal screws into the post. The surgical site was infiltrated with Marcaine and a sterile dressing applied. The operative extremity was placed in a CAM boot or posterior splint on the table.

Post-Operative Method – Surgeon One

Immediately following surgery, patients are to remain non-weightbearing in a Controlled Ankle Movement (CAM) boot or posterior splint with the use of crutches or a knee scooter. Patients are then seen for follow-up on post-operative day #8 and dressings and sutures are removed and steri-strips applied. Patients are to remain in the CAM boot but allowed to balance on heel while standing or use crutches or a knee scooter. At 4 weeks post-operatively, if x-rays revealed proper alignment and progressive healing, patients are allowed full weightbearing in the CAM boot. At approximately 7 weeks the boot can be removed and patients are allowed to progress into a sneaker. Physical therapy is then started (2-3 visits over a 30-day period). At 3 months post-operatively, radiographs should reveal proper consolidation at the fusion site and excellent deformity correction.

Post-Operative Method – Surgeon Two

Patients are seen approximately 1 week following surgery for dressing change and radiographs. At 2 weeks post-operatively, the sutures are removed and patients are transitioned to gradual weightbearing in a CAM boot. In addition, physical therapy is initiated at this time. Patients return at approximately 6 weeks for radiographs. If adequate bone healing across the arthrodesis site is noted, then patients are allowed to progress into a sneaker as tolerated. Final radiographs are obtained at approximately 3 months post-operatively.

RESULTS

This study included 65 patients and 71 procedures (*See Table 1*), six patients had both feet repaired in the study time frame. No bilateral surgeries were performed simultaneously. The average age at the time of surgery was 48 years. There were 58 female procedures and 13 male, with 38 right feet and 33 were left.

The average pre-operative IM angle was 14.7 degrees (range, 9 to 30 degrees) with a noted post-operative improvement of 9.1 degrees (range, 1 to 23 degrees). The pre-operative tibial sesamoid position (TSP) average was 5.3 and improved to 2.4, with an average improvement of 2.9. The average hallux abductus angle improvement was 17.4 degrees, with the pre-operative average of 27.5 degrees and the post-operative average of 10.1 degrees.

Patients were allowed to be begin full weightbearing in a CAM boot between 15 and 43 days with the average time being 25.1 days post-op. Time to progress out of a boot and into a sneaker ranged from 32 to 71 days with an average of 49.2 days.

Complications included wound dehiscence (6), neuritis (2), hardware failure (4), asymptomatic nonunion (4), and cuneiform fracture (1). Clearly, nonunion is the most significant and concerning of these complications. In each of the 4 cases of nonunions, the patients were eventually asymptomatic and demonstrated 1 or 2 screw failures. None of the nonunions required revisional surgery. The asymptomatic nonunion rate was 5.6%.

DISCUSSION

The modified Lapidus arthrodesis has been a well-established technique for the surgical correction of hallux abductovalgus deformity. The procedure has been utilized for the treatment of severe and recurrent bunion deformity, hypermobile first ray, and insufficiency of the first ray. The modified Lapidus arthrodesis has gained recent popularity in literature. Despite the effective reduction of the intermetatarsal angle and bunion deformity, the procedure can be technically challenging as well as associated with some disadvantages. Some of these drawbacks include a prolonged non-weightbearing or immobilization period, nonunion and challenges with reliable fixation.[2-16,18-27]

Albrecht first described the first tarsometatarsal joint arthrodesis procedure in 1911[1], although Lapidus popularized the technique in 1934.[17] Interestingly, the first tarsometatarsal joint

arthrodesis was fixated with number zero chromic catgut and employed immediate weightbearing in a leather soled shoe.[17] The procedure was initially associated with a high rate of nonunion.[5] For many years, the conventional post-operative approach consisted of several weeks of immobilization and non-weightbearing to allow for bone consolidation in order to limit the risk of nonunion and first metatarsal elevation. Although, there are inherent risks associated to prolonged immobilization including deep vein thrombosis, pulmonary embolus, and disuse osteopenia.[3,22,23] In an effort to mitigate these risks, several authors have discussed an early weightbearing protocol.[3-5,7-9,12,13,16,22,26,27] Recent advances in methods of fixation have allowed for this change in post-operative protocols. A multicenter study of 340 patients by Prissel et al[22] revealed that early weightbearing following a modified Lapidus arthrodesis utilizing various fixation constructs did not increase the risk of nonunion. A clinical study by King et al[16] evaluated 136 patients utilizing a two crossing screw fixation construct and early weightbearing at an average of 12 days. The authors reported a nonunion rate of 2.2%. Blitz et al[4] retrospectively reviewed 80 cases of Lapidus arthrodesis where the patients began protected weightbearing at a mean of 14.8 days. The authors utilized a 2 or 3 fully threaded screw construct and reported a 100% union rate.

Since the original procedure, there have been several developments and evolutions in the methods and techniques for fixation.[2-7,9-16,18-27] The methods of fixation have included Kirschner wires, staples, crossed screws, plates and external fixation. As technology has continued to improve, several authors have described techniques and modern fixation constructs to allow for early weightbearing.[2-11,13-16,18,21-23,25-27] In a retrospective review, Saxena and colleagues[23] compared crossed lag screws versus a dorsal-medial locking plate and plantar lag screw in 40 patients (19 patients in the crossed screw group and 21 patients in the plate with plantar lag screw group) that underwent a Lapidus arthrodesis. The authors reported no significant difference in the post-operative complications between the 2 groups, however the plate group was allowed to return to weightbearing 2 weeks earlier. DeVries et al[9] reviewed 143 patients with a Lapidus arthrodesis and compared results on crossed screw fixation versus a dorsal-medial locking plate fixation with or without lag screw fixation. The authors demonstrated that early weightbearing and locking plate construct had a 98.5% union rate while the crossed screw construct had an 89.4% union rate. In another study, Sorensen et al[26] reviewed 21 patients following a Lapidus arthrodesis with a dorsal-medial locking plate (19 patients also received an interfragmentary screw). The average time to ambulation was 2 weeks with a fusion rate of 100%. Cottom and Vora[7] published results on 88 cases of Lapidus arthrodesis using a plantar interfragmentary screw and medial locking plate. The fixation construct allowed for early weightbearing with a mean of 10.9 days and a 97.73% union rate.

Nonunion is one of the common complications associated to the Lapidus arthrodesis. The incidence of nonunion has been reported to range from 0% to 12%.[5,8-10,18,20] Patel and colleagues[20] reported a nonunion rate of 5.3% in 227 cases who received a modified Lapidus arthrodesis. The authors performed the procedure using curettage joint preparation and crossed screw fixation. The patients remained non-weightbearing for 6 to 8 weeks. Klos et al[13] published results on a modified Lapidus arthrodesis with a plantar plate and compression screw in 59 cases. The authors reported a 1.69% nonunion rate with the patients immediately

weightbearing following the procedure. In a retrospective review, Barp and colleagues[2] reported on 147 procedures that underwent a first tarsometatarsal joint arthrodesis utilizing a variety of fixation techniques including an intraplate compression screw fixation, crossing solid core screw fixation, and a single interfragmentary screw with a simple locking plate. The overall nonunion rate was 6.7%.

The InCore Lapidus System is a novel 3-piece construct for fixation of the Lapidus arthrodesis. The system allows for correction in all 3 planes and "precompression" of the arthrodesis site prior to placement of the final fixation. The system features a 5.9mm post placed in the medial cuneiform and two targeted headless compression screws which lock into the cuneiform post. Additionally, one of the primary benefits of the device is the compression/distraction provided by the targeting guide arm that will assist the surgeon in joint preparation. One of the distinct advantages of this system is that it allows for preparation of the joint and fusion site with either planal resection or curettage based on surgeon preference.

In the current study, weightbearing in a CAM boot started as early as 15 days, with an average start time of 25.1 days. While this is 1-2 weeks later than other reported studies, some of the delay could be contributed to the notion this was a new and novel construct and a degree of caution was implemented.[5-7,16,26] Wound dehiscence was reported in six patients by one surgeon. Although the wound dehiscence was minor and healed uneventfully with local wound care, it was likely was attributed to minimizing incision length and tension along the skin edges due to the targeting device.

CONCLUSION

The InCore Lapidus fixation system demonstrates similar correction radiographically as other fixation constructs previously discussed throughout the literature. *(See Figures 1-4)* Additionally, union rates and time to weightbearing and time to regular shoe gear are very similar to the previously reported literature. Distinct advantages to the system, such as allowing surgeon preference in joint preparation, visualization, and assistance with deformity reduction, make it a viable fixation alternative to crossing screws or locking plates for Lapidus arthrodesis.

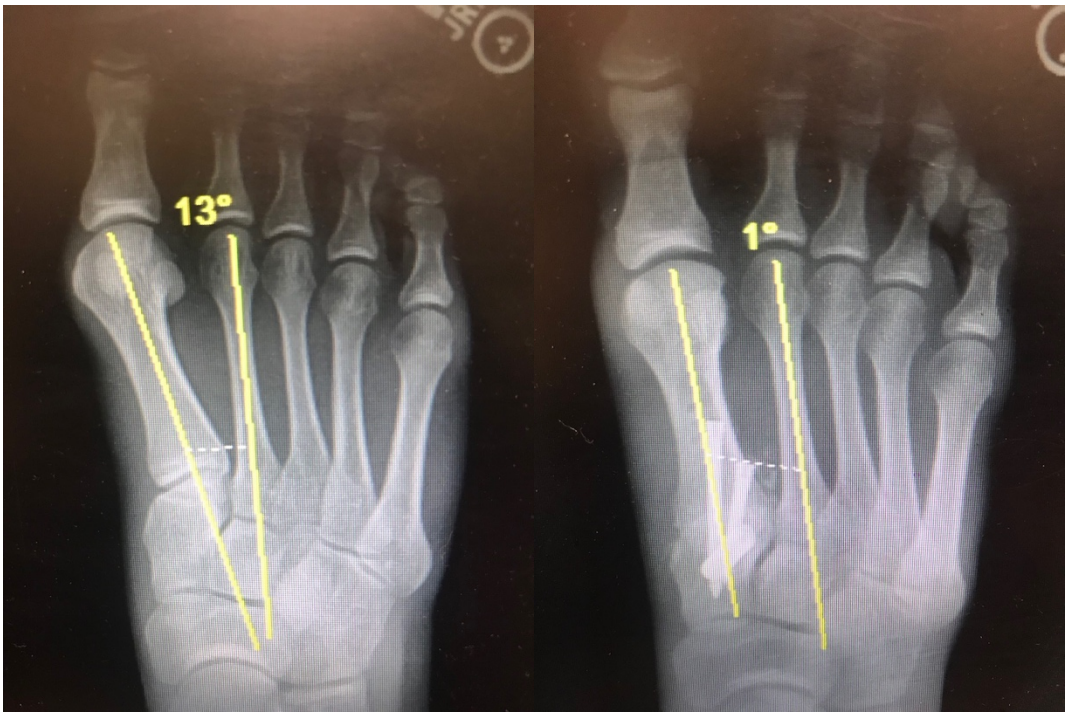

Figure 1. Pre and Post-operative films

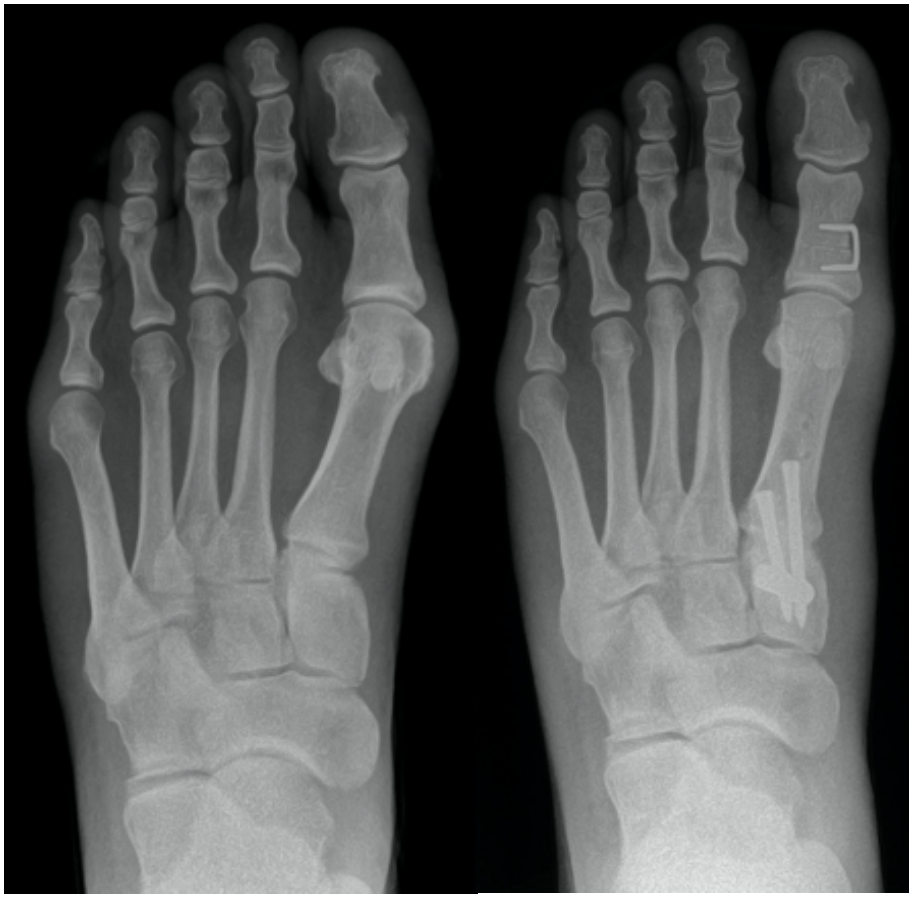

Figure 2. Pre and Post-operative films

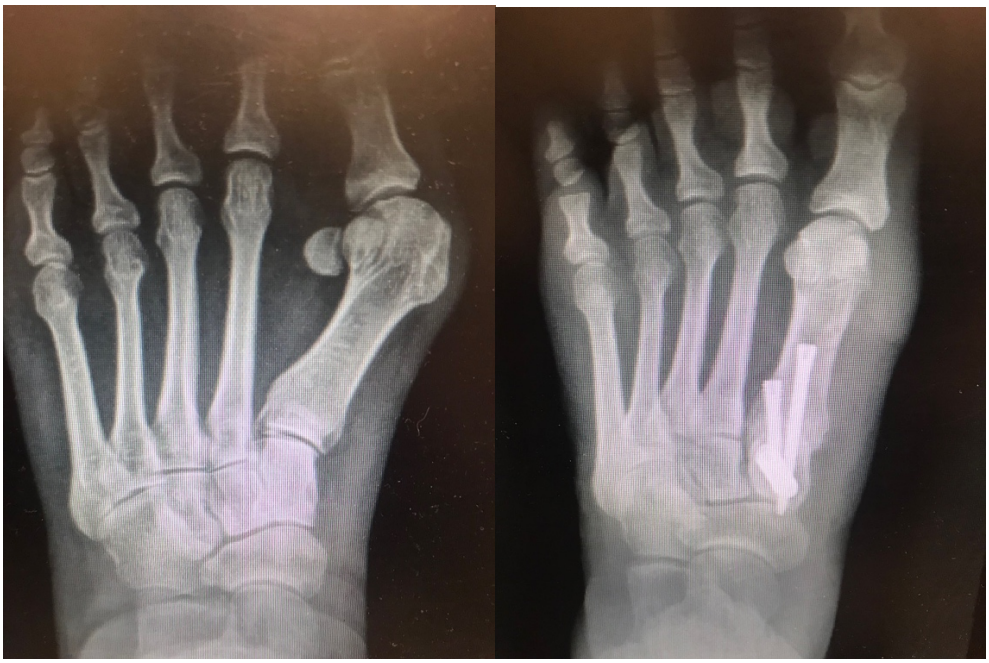

Figure 3. Pre and Post-operative films

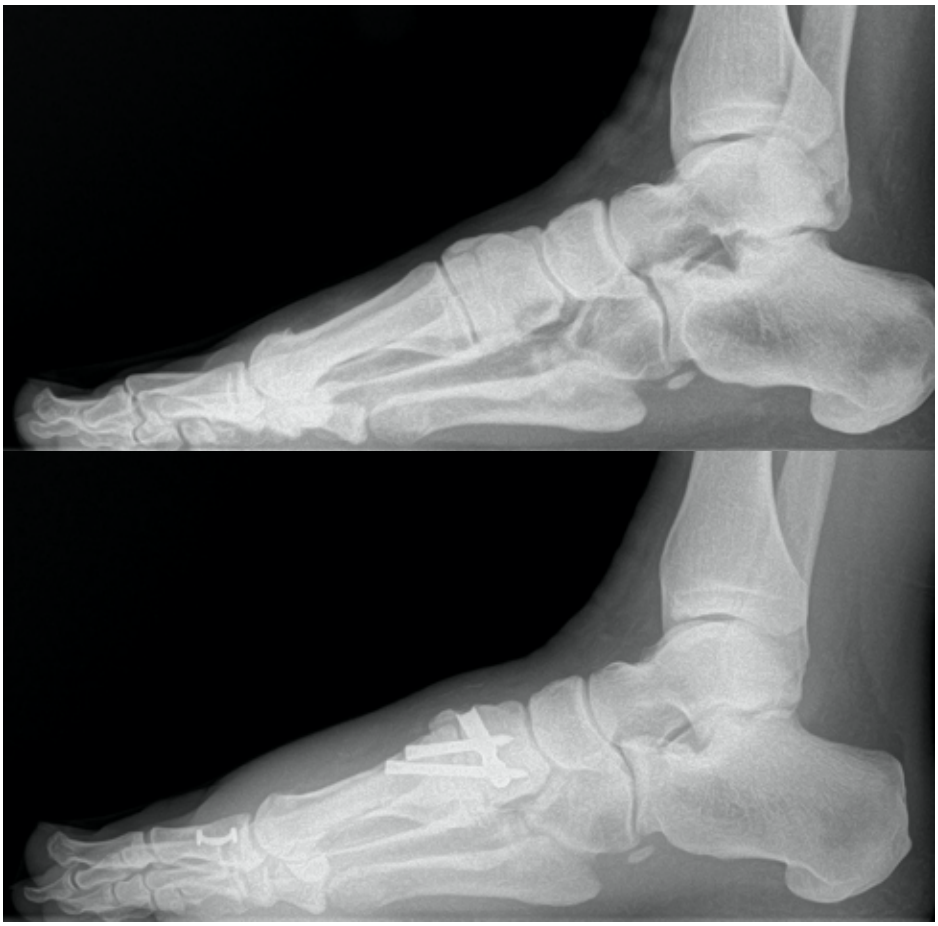

Figure 4. Pre and Post-operative films

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Table 1. InCore Lapidus Results

Age	Sex	Laterality	BMI	Smoking History	Pre-op IM	Post-op IM	IM Change	Pre-op TSP	Post-op TSP	Pre HAA	Post HAA	Days to WB	Days to shoe	Complications
62	M	R	30.4	No	13	5	8	4	2	25	10	27	48	
60	F	L	24.1	No	22	10	12	7	3	37	6	29	50	
53	F	R	27.3	No	13	4	9	6	2	28	16	30	51	
53	F	R	23.9	No	13	3	10	7	3	29	4	30	48	
60	F	L	25.1	Yes	18	9	9	7	3	33	10	30	50	
44	F	L	20.1	No	11	7	4	6	4	29	20	36	50	
55	F	L	25.8	No	15	8	7	6	3	33	22	29	50	
54	M	R	36.3	No	16	7	9	6	3	19	0	27	50	
48	F	R	23.3	No	13	1	12	6	2	29	6	29	50	
60	F	R	20.6	No	14	9	5	6	3	26	13	29	51	Asymp. Radiographic nonunion
60	F	R	25.1	Yes	17	8	9	6	3	30	9	30	48	Partial cuneiform fracture
36	M	R	33.9	No	18	7	11	4	2	35	17	29	50	
57	F	L	23.8	No	13	7	6	6	2	26	13	30	50	
15	F	R	21.3	No	12	4	8	6	3	26	11	27	48	
58	F	R	24.2	No	11	1	10	4	2	27	2	30	50	
69	F	R	35	No	17	6	11	6	2	28	10	43	71	
60	F	R	24.1	No	16	7	9	6	2	36	9	27	48	
53	F	L	36.9	No	13	9	4	6	3	32	26	27	51	Asymp. Nonunion, hardware failure
54	F	R	22.3	No	18	9	9	6	3	31	23	30	51	
58	F	L	19.6	Yes	22	9	11	6	3	33	14	27	69	
67	M	L	25.9	No	16	10	6	7	5	46	26	36	57	
54	F	R	25.2	No	16	8	8	5	2	33	11	27	48	

26	F	R	19.1	No	14	6	8	6	3	39	13	29	50	
67	F	R	25.7	No	14	9	5	6	3	31	16	27	48	
42	F	L	38.2	No	16	5	11	5	2	34	15	29	51	
25	F	L	25.6	No	11	4	7	5	1	16	2	29	50	
50	F	R	21.9	No	11	4	7	5	2	21	6	23	44	
45	M	R	32.3	No	13	7	6	5	2	38	20	30	51	Asymp. Nonunion, hardware failure
13	F	L	26.2	No	17	4	13	5	1	28	3	27	48	
23	F	L	25	No	16	6	10	4	2	26	8	27	44	
37	F	L	26.5	No	11	5	6	5	1	22	5	29	50	
26	F	L	19.1	No	12	1	11	5	2	22	7	27	48	
54	F	R	29.6	No	16	4	12	5	2	30	3	29	50	
56	F	R	23.2	No	12	3	9	5	2	30	17	23	48	
66	M	L	30.8	No	14	4	10	5	3	30	16	29	50	
28	F	L	21.9	No	10	2	8	4	2	24	10	27	48	
13	F	R	26.2	No	13	4	9	4	2	24	7	27	48	
17	M	R	21.5	No	13	4	9	4	1	21	11	27	48	
69	F	R	21.6	No	16	3	13	5	2	33	10	29	57	
67	M	R	25.9	No	14	5	9	6	2	41	12	27	48	
52	F	L	30.3	No	26	3	23	7	2	46	6	27	50	
37	F	R	26.5	No	13	2	11	5	2	20	1	36	64	
62	F	L	27.5	No	19	3	16	6	2	30	8	27	48	
48	F	R	38.7	No	12	7	5	4	2	20	9	27	48	
43	F	R	24.2	No	14	6	8	4	2	27	7	21	40	
37	M	L	37.6	No	20	14	6	6	4	35	18	29	N/S	
25	F	R	30.8	No	12	5	7	5	1	14	0	36	65	
54	F	R	25.6	No	11	1	10	5	1	18	0	26	50	

47	F	L	22.2	No	15	5	10	5	1	19	-4	26	48	Asymp. Nonunion, hardware failure
42	F	R	38.2	No	15	5	10	6	3	27	12	29	51	
53	F	L	27.3	No	14	5	9	5	1	22	6	16	41	
35	F	R	21	Yes	21	6	15	7	5	53	12	15	47	Neuritis
46	F	L	22.1	Yes	21	8	13	5	4	20	12	17	34	
19	F	R	21.1	No	14	5	9	6	2	22	4	18	44	
57	M	L	24.3	No	14	8	6	4	3	20	4	17	35	
58	F	R	20.2	No	12	7	5	4	3	6	5	17	42	
22	F	L	25.1	No	16	8	8	5	3	23	1	15	37	Wound dehiscence; Neuritis
63	F	R	25.8	No (quit)	13	2	11	6	3	17	1	17	48	
46	F	R	28.3	No	12	7	5	3	1	15	12	17	49	
65	M	L	24.4	No	14	5	9	6	3	29	15	28	62	Wound dehiscence
66	M	L	25.1	No (quit)	13	7	6	5	2	26	12	17	44	
51	F	L	32	No	12	4	8	5	2	16	0	17	41	
38	F	L	24.2	No	11	4	7	5	2	12	4	16	34	Wound dehiscence
46	M	L	30.5	No	9	8	1	3	3	30	29	17	35	
55	F	R	28.1	No	15	8	7	6	2	24	15	17	69	Wound dehiscence
55	F	L	28.1	No	13	2	11	5	2	26	6	19	65	
37	F	R	28.2	No	30	9	21	6	5	40	17	16	40	
57	F	R	28.1	No	17	5	12	6	2	33	7	17	49	
57	F	L	28.1	No	14	5	9	3	2	26	12	19	62	Wound dehiscence
56	F	L	19.4	No	12	1	11	6	2	24	5	16	47	
37	F	L	32.3	No (quit)	9	4	5	2	2	25	14	17	32	Wound dehiscence