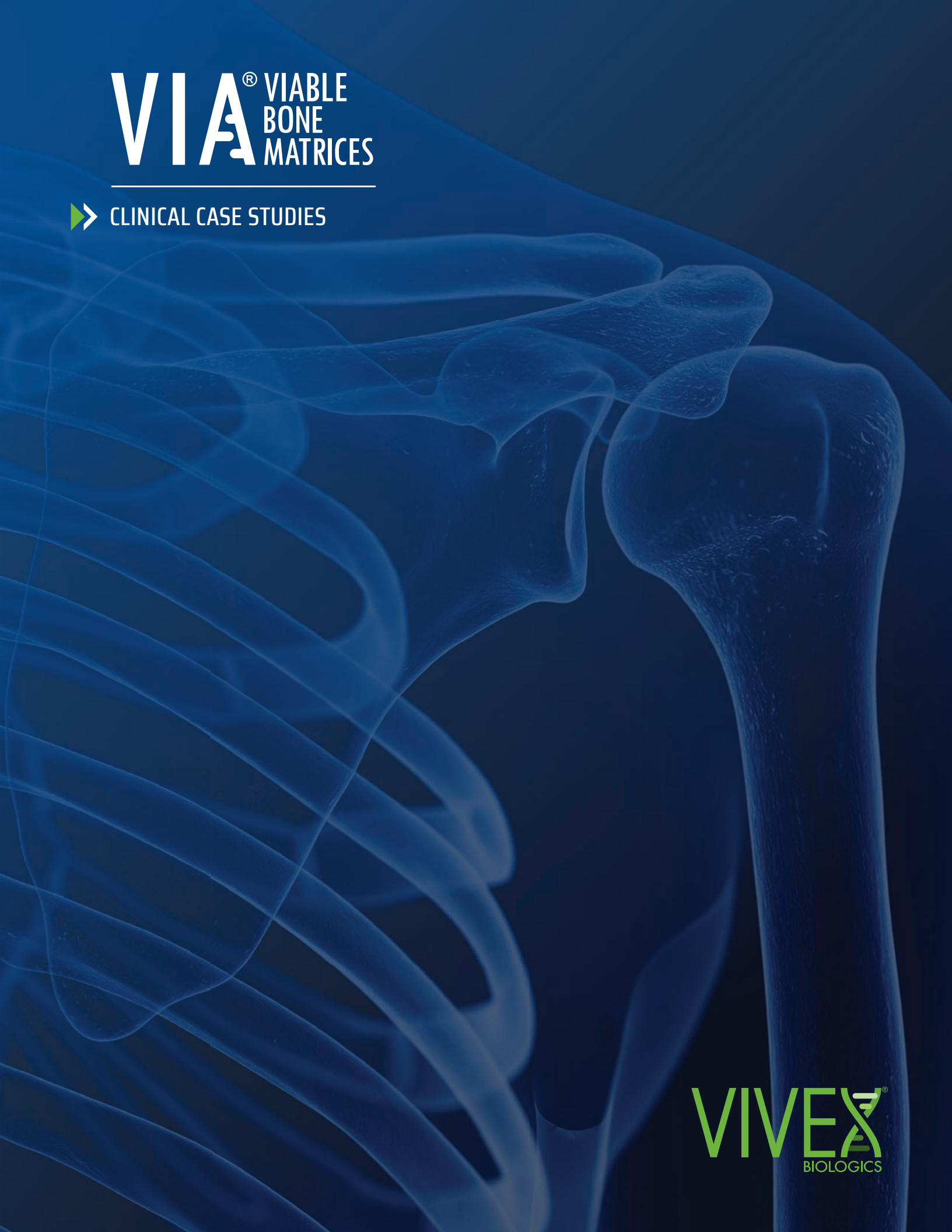
VIA® VIABLE BONE MATRICES

CLINICAL CASE STUDIES

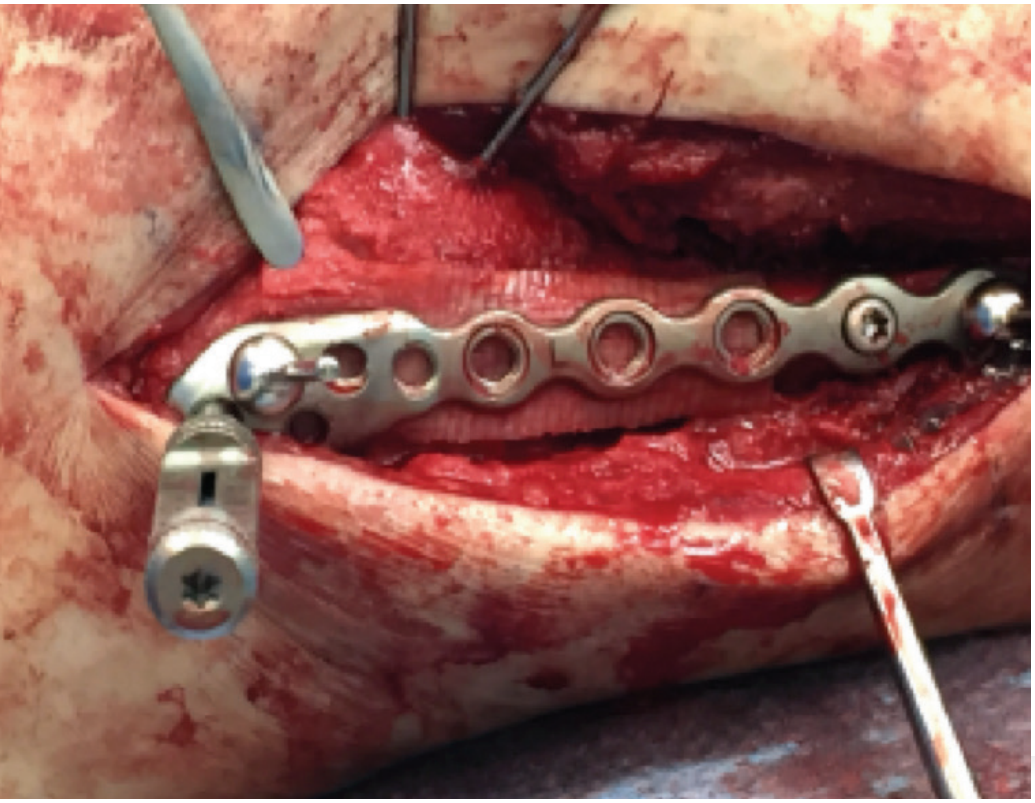


VIVEX BIOLOGICS

VIA® GRAFT VIA® GRAFT MOLDABLE VIAFORM® VIAFORM® MOLDABLE

PRELIMINARY CLINICAL EXPERIENCE

Since its inception in 1970, VIVEX® Biologics has distributed over two million allografts across all 50 states and to 18 countries worldwide without a case of disease transmission. After two years of VIA Graft Viable Bone Matrix distribution, the VIA product line was expanded to include different scaffold options. The formulation of additional scaffold blends led to the widespread adoption of the VIA Viable Bone Matrix product line across several different surgical specialties. Implantations have occurred in a range of clinical applications including spinal fusion, foot and ankle fracture repair, upper extremity fracture repair, oral and maxillofacial reconstruction, and oncological reconstruction *[Figure 1]*. The initial implantations of the VIA Viable Bone Matrices have been closely followed and physicians have actively assessed potential graft-related complications. To date, the impeccable safety record established by VIVEX for allograft distribution has been sustained, as no graft-related adverse events have been reported.



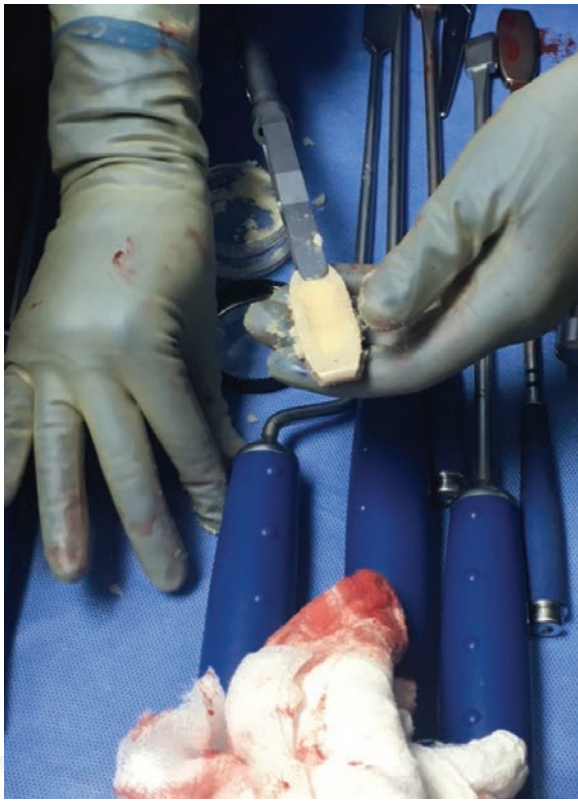


Figure 1: Clinical Use of VIA Viable Bone Matrix

CASE 1

LATERAL LUMBAR SPINE FUSION

WILLIAM TALLY, MD

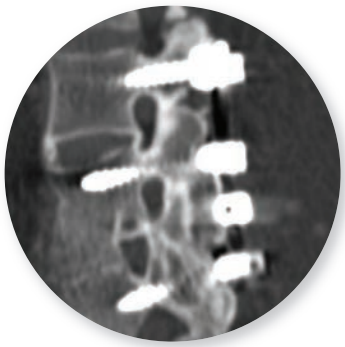
A 53-year-old female with a history of adjacent segment disease and facet arthrosis at the L3-L4 level following an L4-S1 spinal fusion with pedicular fixation.

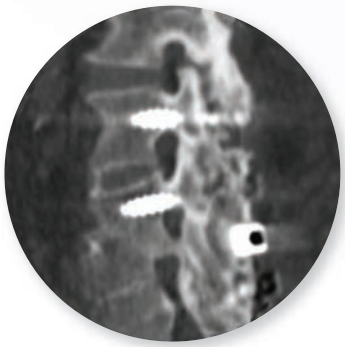
PREOPERATIVE IMAGING

Preoperative CT scan demonstrated severe bilateral facet arthropathy with calcification of the ligamentum flavum resulting in thecal sac compression and severe central canal stenosis.

PROCEDURE

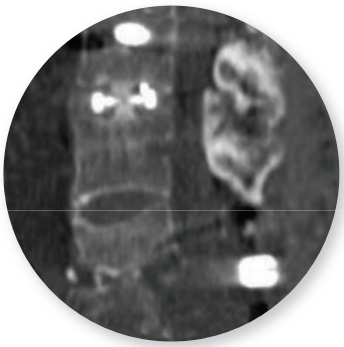
A lateral lumbar interbody fusion was performed at the L3-L4 level to extend the fusion. VIA Graft Viable Bone Matrix was packed into the dual chambers of the interbody device prior to insertion. Following device insertion, posterior pedicle screw fixation was used for additional lumbar stabilization with a combination of ceramic bone graft substitute and VIA Graft, along with patient bone marrow concentrate.



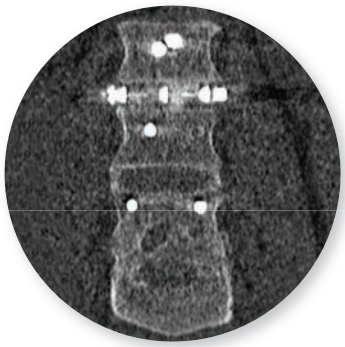


SIX-MONTH CT SCAN ASSESSMENT

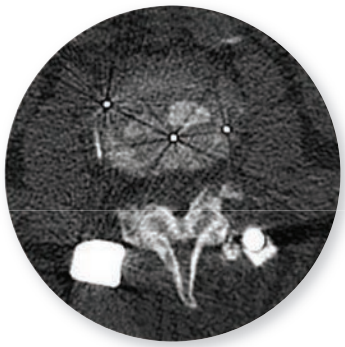
Bone fusion with mineralization of the graft material across the disc space in the interbody implant chambers, with very robust bone strongly present in the most proximal chamber of the device. No evidence of osteolysis, heterotopic bone, or graft site inflammation.



Sagittal



Coronal



Axial

CASE 2

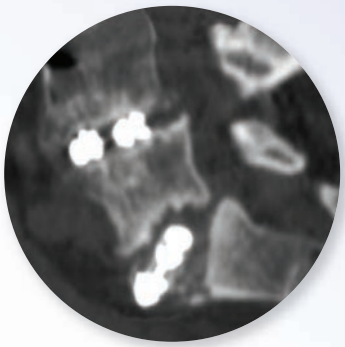
ANTERIOR LUMBAR SPINAL FUSION

WILLIAM TALLY, MD

A 78-year-old female presented with a history of back pain and left leg pain and prior lumbar fusion surgery at L4-L5 and L5-S1 levels. Patient fell approximately five months after surgery. Pseudoarthrosis, pedicular fixation loosening, and bony neural foraminal stenosis were present at the L5-S1 level. Trace antero-listhesis of L5 on S1 was also noted.

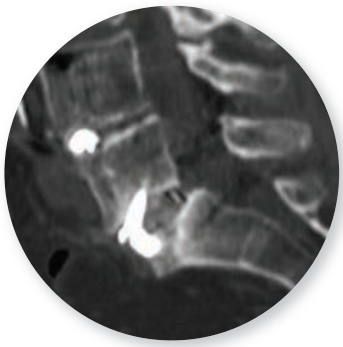
PROCEDURE

An anterior lumbar interbody fusion with supplemental anterior plating device was performed at the L5-S1 level. VIA Graft Viable Bone Matrix was packed into the central chamber of the interbody device prior to insertion. Additional VIA Graft was packed around the device after insertion. Following device insertion, posterior pedicle screw fixation was used for additional lumbar stabilization with a ceramic bone graft substitute with patient bone marrow concentrate.

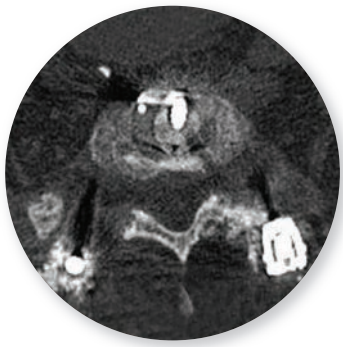


6 MONTH CT SCAN ASSESSMENT

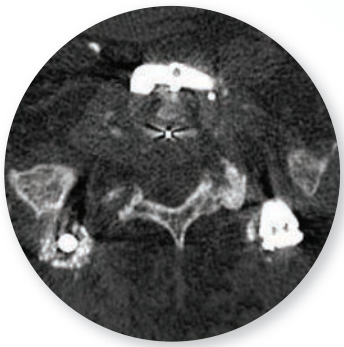
Bony fusion was evident across the interbody space with mineralization of the graft material within the interbody implant. Robust bone mineral present not only within the central chamber of the device but also lateral to the device. No evidence of osteolysis, heterotopic bone, or graft site inflammation was present.



Sagittal



Axial



Axial

CASE 3

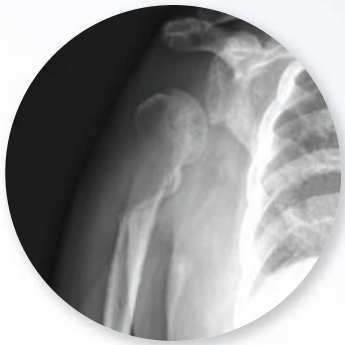
EXTREMITY CASE

H. THOMAS TEMPLE, MD

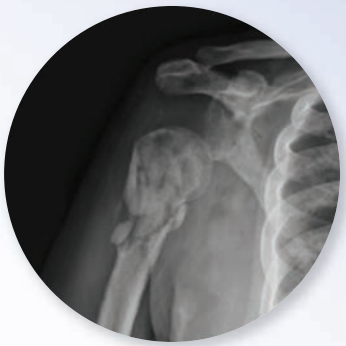
A 53-year-old male presented with intractable pain from a lytic lesion of the right proximal humerus.

PROCEDURE

VIA Graft Viable Bone Matrix and allograft morselized cortical bone chips were packed into the lesion site.



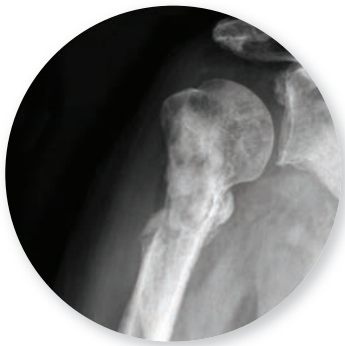
Preoperative Imaging



Two-Week Postoperative Image

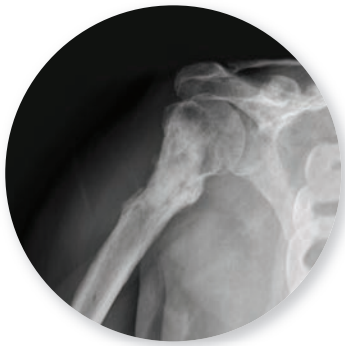
10-WEEK X-RAY

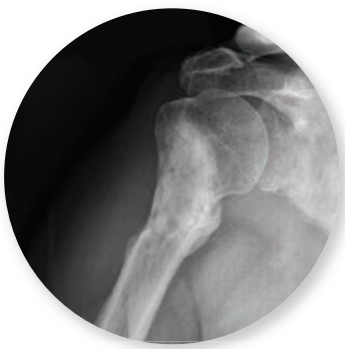
Bone graft consolidation is apparent with mineralization of the graft material at the fracture site. There is healing and filling of the defect. No evidence of osteophyte formation or graft site inflammation or seroma.



ONE-YEAR POSTOPERATIVE IMAGES

Bone graft is fully incorporated and the defect has been filled. Normal usage of the shoulder has been restored.





CASE 4

ALLOGRAFT HOST-JUNCTION SITE FRACTURE – REVISION

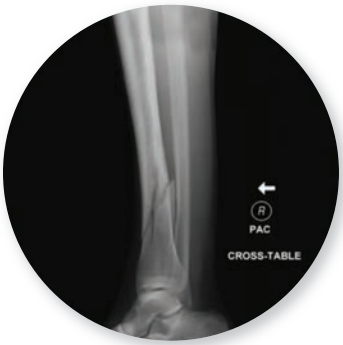
H. THOMAS TEMPLE, MD

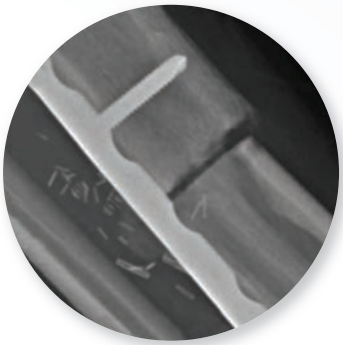
A 38-year-old male with pathologic fracture through a low grade osteosarcoma (image below) was referred after sustaining a fracture during a skiing trip. Fracture due to inadequate fixation of the graft and a substantial fracture gap in the proximal allograft-host junction site.

PROCEDURE

Initially, the bone was resected along with adjacent soft tissue. Reconstruction was performed using an intercalary cortical allograft and vascularized fibula that was stabilized with a distal tibial locking plate. Later, due to persistent pain and radiographic non-union at the proximal allograft junction, surgery was recommended using VIA Graft Viable Bone Matrix.

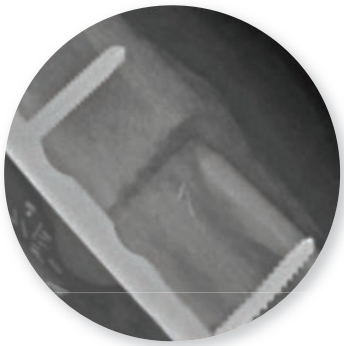
The fibrous interface at the non-union site was debrided and a high-speed burr was used to create a bleeding surface on the host bone interface. A cortical non-locking screw was placed to engage the allograft and provide sufficient purchase and stability. The defect was then packed with the VIA Graft.

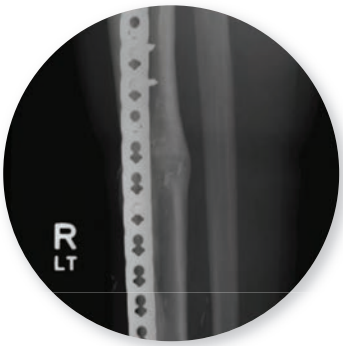




RADIOGRAPHIC ASSESSMENT

Radiographically, bone formation at the interface of the allograft was robust with periosteal bridging between the native bone and the allograft at 5 and 10 month assessment. This treatment, including the use of VIA Graft, accommodated an assertive return to function, which further stimulates bone modeling. There was no evidence of heterotopic bone at the graft placement site, and osteogenic activity aligned with dynamic loading.





CASE 5

LISFRANC ARTHRODESIS

JESSE YURGELON, DPM

A 50-year-old male who sustained a Lisfranc injury that was missed upon initial evaluation. Due to a delay in diagnosis of greater than 4 weeks, the recommendation for treatment was tarsometatarsal arthrodesis.

INTRODUCTION

Lisfranc fracture/dislocations are a common injury encountered by foot and ankle surgeons. The incidence for these injuries is approximately 1 in 55,000, but the incidence of those injuries missed in acute care settings is up to 25%.[1] The delay in diagnosis can cause prolonged morbidity and can lead to painful midfoot arthritis including deformity. Treatment options are often determined by the type of injury, activity level of the patient and other co-morbidities. Operative treatment is typically employed over non-operative treatment for Lisfranc injuries due to the associated morbidity. Specific long-term complications associated with Lisfranc injuries include pain and swelling due to the development of midfoot arthritis, which is often treated with midfoot arthrodesis.

PATIENT HISTORY AND ASSESSMENT

X-ray and CT imaging studies confirmed comminuted intra-articular fractures of the 1st through 3rd tarsometatarsal joints *[Figure 1A, 1B, & 1C]*. Treatment options were discussed with the patient and Lisfranc arthrodesis of the 1st through 3rd tarsometatarsal joints was elected to be performed. Given the delay in diagnosis, comminuted nature of the fracture pattern, and the patient's co-morbidities of smoking and Vitamin D deficiency, a novel viable bone matrix was chosen to minimize the risk of a delayed union or non-union. VIA Form Moldable was used to aid in healing as a bone void filler due to its osteoconductive, osteoinductive, and osteogenic properties.

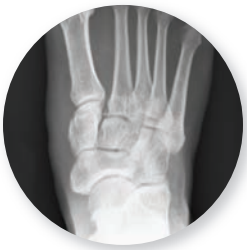


Figure 1A

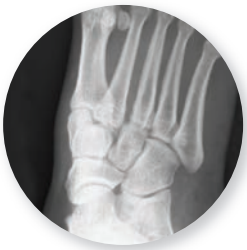


Figure 1B

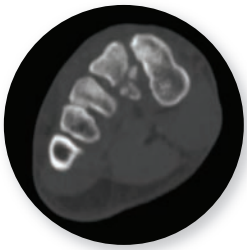


Figure 1C

Figure 1A: AP weight-bearing x-ray shows subtle fleck and diastasis between the base of the 2nd meta-tarsal and medial cuneiform.

Figure 1B: Oblique weight-bearing x-ray shows incongruity of the 3rd metatarsal on the lateral cuneiform indicating instability. The 2nd metatarsal and middle cuneiform instability is further demonstrated on the oblique X-ray.

Figure 1C: CT scan demonstrates comminution of the base of the 2nd metatarsal consistent with Lisfranc injury.

PROCEDURE DETAILS

The 1st through 3rd tarsometatarsal joints required significant debridement of tissue. Joint preparation was performed by removing the associated cartilage and comminution of the fracture fragments. The joints were prepared using curettage and fenestration of the subchondral plate followed by a fish scaling technique. VIA Form Moldable was prepared on the back table and placed into the bone void prior to fixation *[Figures 2A, 2B, 2C, & 2D]*.

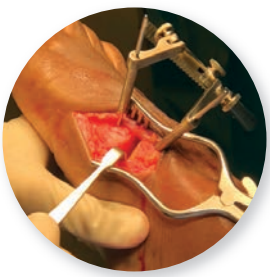


Figure 2A

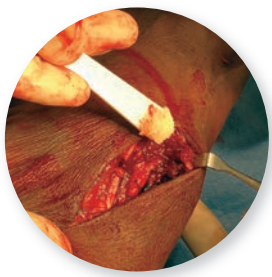


Figure 2B

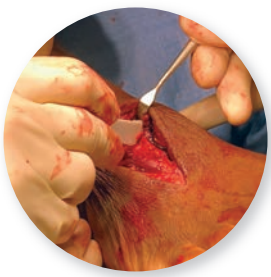


Figure 2C

Figure 2D

OUTCOMES MEASUREMENTS

Visual Analogue Scale (VAS) and Activity. Patient initially presented with a day-to-day VAS of 7/10 while continuing to ambulate since his injury. At 2 weeks, he was comfortable following surgery with a VAS of 4/10 and continually improving. By week 12, his VAS was reported as 1/10 and he was moving around in regular shoes and slowly resuming normal activities including international travel for work. During his final post-operative visit at 6 months, the patient was discharged from formal physical therapy and permanently back in regular shoes, while also resuming all activities in which he was able to engage prior to his injury.

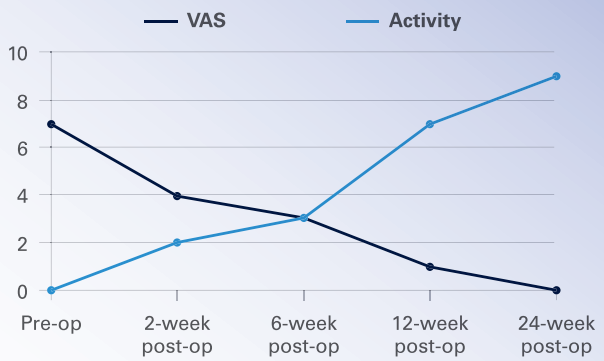


Figure 3: Visual Analogue Scale Progression

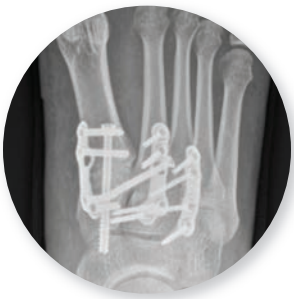


Figure 4A

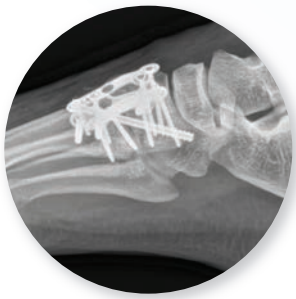


Figure 4B

Figures 4A + 4B: 2-week post-operative X-rays show reduction of the tarsometatarsal joints with hardware intact. VIA Form Moldable Viable Bone Matrix was used to augment the arthrodesis sites.

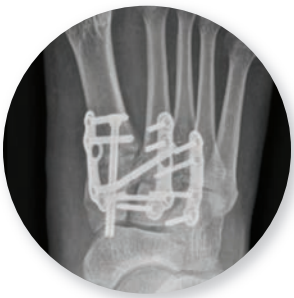


Figure 5A

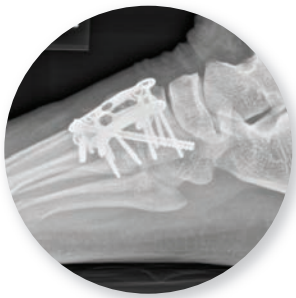


Figure 5B

Figures 5A + 5B: 6-week post-operative X-rays show further incorporation of the arthrodesis sites, which allows the patient to be transferred to a protected walking boot. The patient is cleared to participate in physical therapy with transition from a walking boot into a shoe as his swelling permits over the next several weeks.

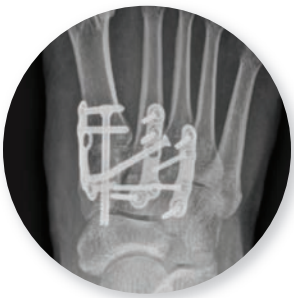


Figure 6A

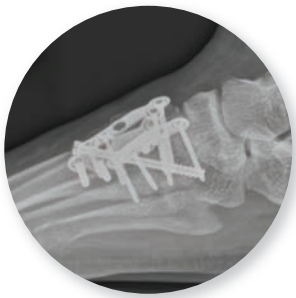


Figure 6B

Figures 6A + 6B: 12-week post-operative X-rays show complete osseous consolidation of the arthrodesis sites and no pain or swelling with palpation or manipulation of the surgical sites.

OUTCOME/ANALYSIS

This midfoot arthrodesis case study illustrates the use of VIA Form Moldable as a bone void filler in repair of traumatic foot and ankle injuries where comminution and bone loss are encountered.

CASE 6

TALONAVICULAR FUSION

JUDITH BAUMHAUER, MD, MPH

A 72-year-old woman with rheumatoid arthritis and concurrent thyroid disease presents with daily walking pain in the right foot near the ankle.

CLINICAL HISTORY

A 72-year-old woman with rheumatoid arthritis and concurrent thyroid disease on Prednisone (10 mg/day), Enbrel, Hydroxychloroquine, and Synthroid presents with daily walking pain in the right foot near the ankle. She has limited and very painful hindfoot motion (inversion/eversion; abduction/adduction) but near normal ankle motion with minimal pain. Tenderness and swelling is located over the talonavicular joint.

Lateral right foot x-ray demonstrates end stage talonavicular arthritis *[Figure 1]*. The patient has previously tried an ankle brace and a cortisone injection *[Figure 2]* without relief. A talonavicular fusion is recommended.

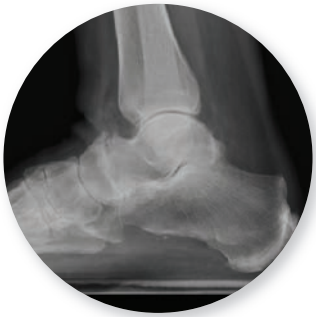


Figure 1

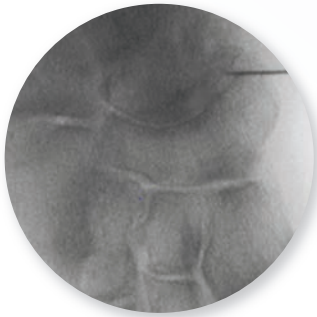


Figure 2

Figure 1: Right standing lateral ankle X-Ray demonstrating severe talonavicular arthritis.

Figure 2: Cortisone injection to the right talonavicular joint under fluoroscopy guidance.

APPLICATION OF VIA Graft

Due to the patient's risk factors for non-union (Prednisone, Enbrel, and thyroid disease), bone graft supplementation was planned. The patient was taken to the operating room and under a popliteal block, a dorsal incision was made over the talonavicular joint and an open arthrotomy was performed. A distractor was used to visualize the joint surfaces and there was extensive cartilage loss and soft subchondral bone. The surfaces were prepared and a K-wire was used to fenestrate the bone to promote healing. VIA Graft 2.5 cc was placed into the talonavicular joint and a partially threaded screw was used to compress the joint medially along with a dorsal 4-hole plate with added compression *[Figures 3a + 3b]*. A sterile post-op dressing and a short leg splint were applied.

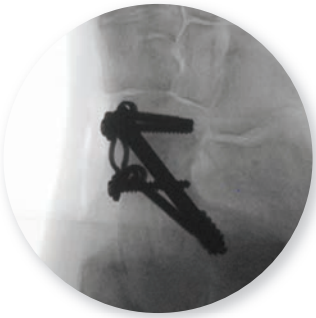


Figure 3a

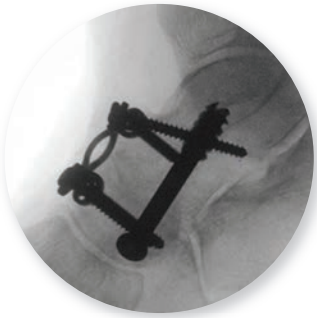


Figure 3b

Figures 3a + 3b: Intra-operative fluoroscopy images of right foot after talonavicular arthrodesis.

POSTOPERATIVE

Postoperatively, the patient was placed non-weightbearing for 6 weeks and then a walking cast was used for 2 weeks and repeat x-rays were obtained *[Figures 4a + 4b]*. A physical exam at 8 weeks demonstrated no pain, no motion, and no swelling in the area of the surgery. The patient was placed into an ankle brace and physical therapy was implemented. Postoperative Patient Reported Outcomes scores [PROMIS physical function, pain interference and depression (mood)] demonstrated marked improvement of pain after 8 weeks and progressive improvement in function at this early time point.

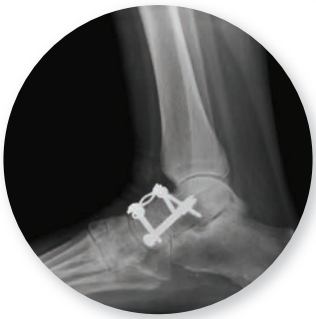


Figure 4a

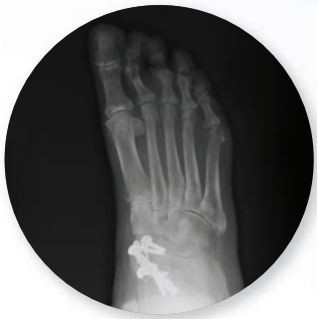


Figure 4b

Figures 4a + 4b: Standing right lateral and oblique foot films 8 weeks after talonavicular arthrodesis demonstrating progressive fusion and bony bridging.

OUTCOME

This patient had multiple risk factors for developing a non-union. The talonavicular joint is the most vulnerable joint for non-union in the hindfoot. In addition, this patient was taking medications known to lead to poor bone healing. Despite these risk factors, use of VIA Graft in this patient resulted in documented improvement in patient outcomes *[Figure 5]*.

Figure 5: Patient-Reported Outcomes

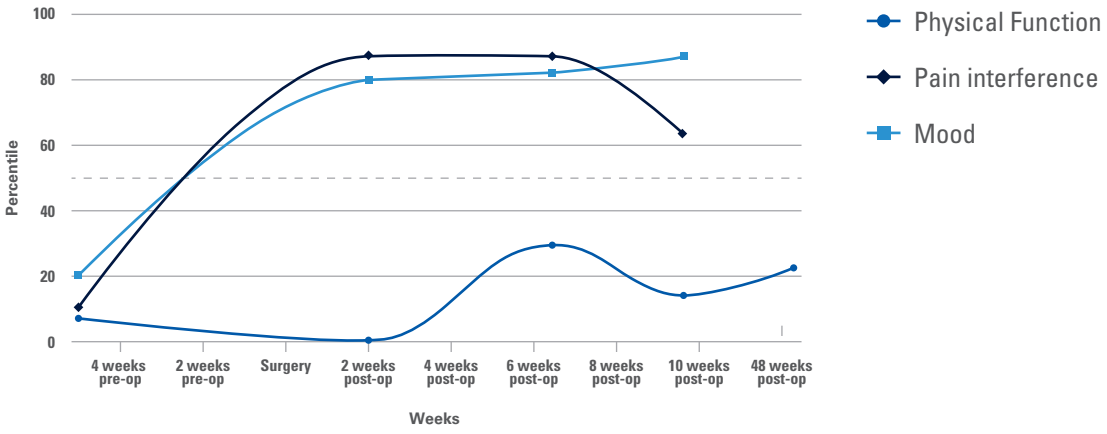


Figure 5: Graphic display of patient reported outcome scores [PROMIS physical function, pain interference, depression (mood)] over time. The patient first presented at 4 weeks pre-op and surgery was performed 4 weeks later, with the first follow-up visit occurring at 6 weeks post-op. Pain and mood improved over surgical recovery and at 8 weeks post-op, the patient's function was improving greatly. The patient was out of the cast by 8 weeks post-op and began physical therapy, maintaining her functional improvement.

CASE 7 + 8

SPINE FUSION

BRYAN FOX, MD + DAVID GOSS, MD

Viable Bone Matrix for spine fusion clinical success — comparing two surgical techniques

INTRODUCTION

The current gold standard in lumbar fusion calls for transpedicular fixation combined with an interbody placement of autologous bone. Limited availability of autologous bone as well as donor site morbidity have guided the development of supplemental tissue grafts that will optimize treatment efficiency without diminishing therapeutic value. Level I randomized trials comparing efficacy of a DBM preparation (Grafton DBM) with iliac crest autograft demonstrated 86% fusion for the DBM group and 92% for the autograft group.[1] Less positive results have been reported in a contralateral comparison of DBM gel to either autograft or autograft composite in patients undergoing instrumented posterolateral fusion.[2] After two years follow-up, fusion rates of 52% on the DBM side and 54% on the autograft were reported.

This data represents use of VIA Viable Bone Matrices for spine fusion in two surgical practices using different grafting techniques.

RESULTS

Surgeon #1 treated 51 patients and 79 levels, while Surgeon #2 treated 133 patients and 202 levels. Patient demographics were similar in age, diabetes, and tobacco use. Fusion rates were 96% and 98%, respectively, regardless of surgical technique. Technique #1 used a PEEK spacer and supported the posterior with graft and hydroxyapatite collagen sponge. Technique #2 placed an interbody spacer with graft within and surrounding the device in the disc space.

Preoperative VAS for the patients in Surgeon #2's practice was 61.9 (13-100), while VAS 12 months post-operatively was 24.8 (0-71). Two patients in Surgeon #2's practice required fusion extensions because of falls, but the initial sites remained fixed and solid.

DISCUSSION

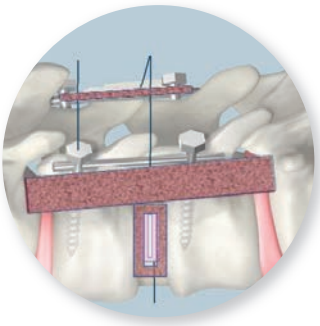
This retrospective review compared two different surgical techniques that both incorporated a viable allograft as a graft extender. While the graft was not used singularly, the composition achieved when using this graft with a living cell component demonstrated efficacy, regardless of the technique or the interbody implant. Based on surgical outcomes, the surgical procedures described here were deemed safe and therapeutically successful in cohorts of 51 and 133 patients.

METHODS

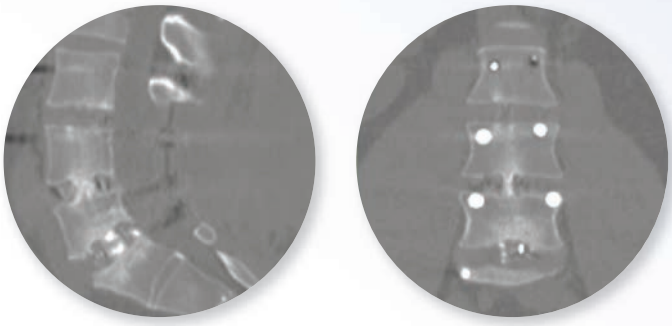
Surgeon #1 blended four components: VIA Graft, local autograft, BMAC, and collagen hydroxyapatite sponge. These components were placed in the posterolateral gutters for patients receiving posterolateral instrumented fusions, and in the posterolateral gutters, interbody spacers, and intradiscal spaces, for patients receiving posterolateral fusions and transforaminal interbody fusions.

Surgeon #2 obtained iliac crest bone marrow and mixed VIA Form Moldable material in a ratio of approximately 5mL of viable allograft to 1mL of bone marrow aspirate, packing approximately 2-3mL of the VIA Form/bone marrow mixture into each disk space. Additional VIA Form Moldable was packed into the interbody spacer that was packed into the interbody spacer to fill the available bone graft window. All exposed bone was decorticated.

TECHNIQUE 1

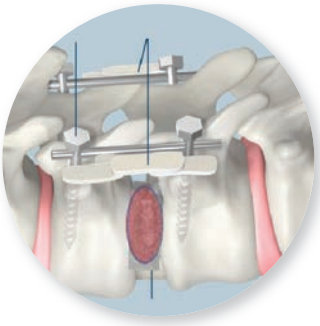


VIA Form Moldable in disc and posterolateral in collagen sponge

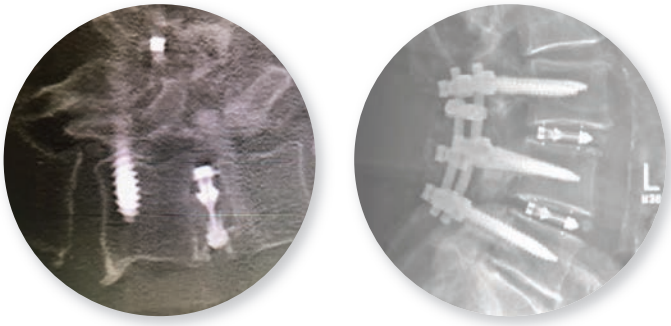


2-level fusion, PEEK Implants 8 months following surgery

TECHNIQUE 2



VIA Form Moldable within disc and within implant



67-year-old male with degenerative spondylosis causing neurogenic claudication. Implants are Globus Caliber® interbody spacer and Globus Creo® pedicle screws.

1. Kang J, An H, Hilibrand A, Yoon ST, Kavanagh E, Boden S. Grafton and local bone have comparable outcomes to iliac crest bone in instrumented single-level lumbar fusions. Spine. 2012 May 20;37(12):1083-91

2. Cammisa FP, Lowery G, Garfin SR, Geisler FH, Klara PM, McGuire RA, Sassard WR, Stubbs H, Block JE. Two-Year Fusion Rate Equivalency Between Grafton® DBM Gel and Autograft in Posterolateral Spine Fusion: A Prospective Controlled Trial Employing a Side-by-Side Comparison in the Same Patient. Spine. 2004 29(6):660-666

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