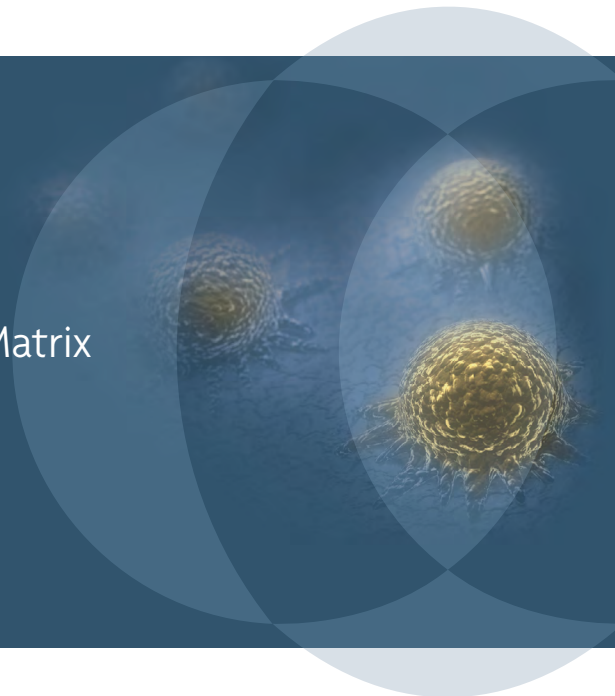
ViviGen®

Cellular Bone Matrix

Clinical Compendium

Use of ViviGen Cellular Bone Matrix in Trauma, Extremity and Craniomaxillofacial Procedures.



DePuy Synthes
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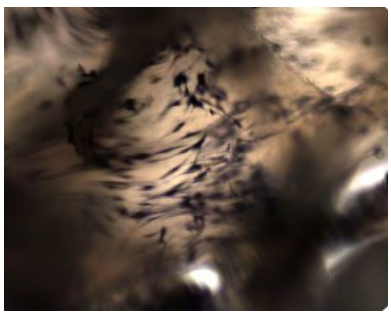
LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

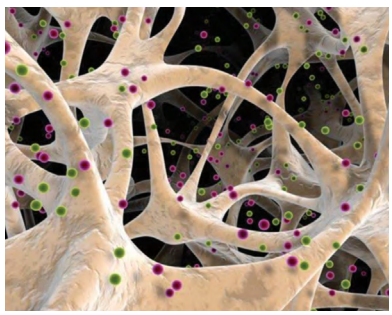
What is ViviGen?

ViviGen is a cellular allograft intended for repair or reconstruction of musculoskeletal defects.[1] ViviGen is being utilized in fusion, non-union, and malunion for foot/ankle, long bone, and craniomaxillofacial trauma and reconstruction in patients with compromised biology. It provides all three elements necessary for bone healing providing an alternative to autograft while avoiding the complications and operating room time associated with autograft.



Osteogenic[2]
Lineage Committed Bone Cells

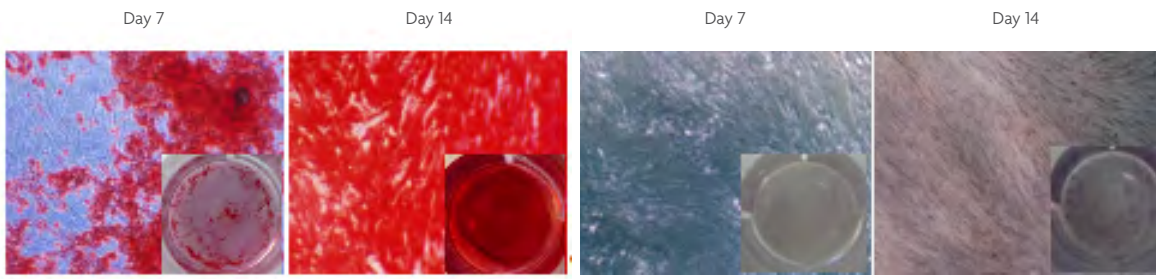
Osteoconductive[2]
Corticocancellous Chips



Osteoinductive[2]
Demineralized Bone

What is the ViviGen advantage?

ViviGen is the first and only cryopreserved cellular allograft focused on protecting and maintaining lineage-committed bone cells. Pre-clinical studies suggest bone cells remain at the defect site longer, directly participate in the bone formation process and deposit a higher quality of bone than mesenchymal stem cells.[3,4] **ViviGen cells are in a state ready to produce calcium deposits to form bone as early as day 7.**[2]



ViviGen-Derived Cells **Mesenchymal Stem Cells (MSCs)**

Cells were fixed and stained for calcium deposits by alizarin red. MSCs were used as a comparative control.

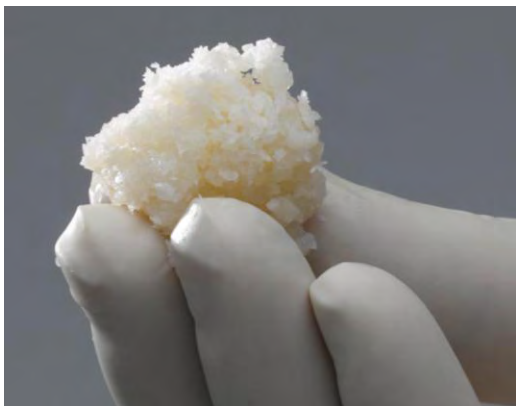
The right cells. The right time. The right forms.

What are the advantages of the ViviGen packaging?

ViviGen's unique and optimized thin wall packaging allows all ViviGen sizes to thaw in 5 minutes or less.[2] This rapid thaw prevents ice crystals from forming within the cell, which maintains viability.[5]

What forms of ViviGen are available?

ViviGen and ViviGen Formable provide the same advantages with alternative formulations to meet surgeons' clinical needs.



ViviGen contains osteoinductive demineralized bone particulate. This particulate allows the graft to be placed into a contained void.

ViviGen Formable contains osteoinductive, precision-machined, demineralized fibers. These demineralized fibers provide a putty-like consistency, allowing the graft to be shaped and molded.

References:

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2. Data on file LifeNet Health 65-0347
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4. Reichert et al. J Tissue Engineering & Regenerative Medicine (2011) 5:831-844.
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Table of contents

Peer Reviewed Publications

Ankle and Foot Arthrodesis using ViviGen 5

Salvage of a Failed Ankle Arthroplasty using ViviGen. 6

Explant Histology Following ViviGen Formable Implantation 7

Case Studies

Trauma

Surgical Repair of Open Femur Fracture with Bone Loss Using ViviGen Cellular Bone Matrix 8

Surgical Repair of a Tibial Metaphyseal Defect Using ViviGen Formable Cellular Bone Matrix. 13

Surgical Repair of Tibial and Fibular Metaphyseal Defects in Pilon Fractures Using ViviGen Cellular Bone Matrix 15

Surgical Repair of a Nonunion Fracture at the Fifth Metatarsal Using ViviGen Cellular Bone Matrix 17

Surgical Repair of a Delayed Union to the Radius Diaphysis Using ViviGen Cellular Bone Matrix in a Division I Football Athlete. 19

Repair of a Comminuted Talar Neck Fracture using ViviGen Formable Cellular Bone Matrix combined with a SymAlign® Cotton Allograft Wedge. 22

Extremity Reconstruction

Ankle and Hindfoot Arthrodesis Using ViviGen Cellular Bone Matrix #1 26

Ankle and Hindfoot Arthrodesis Using ViviGen Cellular Bone Matrix #2. 28

Ankle and Hindfoot Arthrodesis Using ViviGen Cellular Bone Matrix #3. 30

Surgical Repair of Severe Varus Ankle Deformity with Osteoarthritis Using ViviGen Cellular Bone Matrix 32

Salvage of Failed Wrist Arthroplasty Using ViviGen Cellular Bone Matrix 34

Craniomaxillofacial

Mandibular Reconstruction Using ViviGen Formable Cellular Bone Matrix Following Ameloblastoma Resection 37

Surgical Repair of a Mandibular Angle Fracture with Fibrous Union Using ViviGen Cellular Bone Matrix 40

Compendium of approved case study content. Document numbers listed reference the original document.

ARTICLE IN REVIEW:

Ankle and foot arthrodesis using ViviGen®

PUBLICATION: Clinical Research on Foot and Ankle, September 2018

TITLE: A New Approach to Ankle and Foot Arthrodesis Procedures Using a Living Cellular Bone Matrix: A Case Series.

AUTHORS: Roukis TS, Samsell B.

STUDY DESIGN: Case series

RESULTS: With the growing number of foot and ankle arthrodesis procedures performed in the United States, new approaches are needed to reduce the rate of non- or delayed unions and promote high-quality fusion of bone. This case series presents the use of ViviGen in four different types of foot and ankle procedures: ankle arthrodesis, double arthrodesis of the hindfoot, tibiotalocalcaneal arthrodesis, and modified Lapidus to correct hypermobility of the first tarsal-metatarsal joint. All patients demonstrated fusion within 7.5 to 10 weeks postoperative and were weight bearing within 2 to 3 months. The patients reported no postoperative complications and were satisfied with the outcomes. This study demonstrates that ViviGen may be an effective approach for achieving fusion in four types of foot and ankle procedures.

Fusion achieved using ViviGen:

All patients achieved fusion within 7.5 to 10 weeks and were weight bearing within 2 to 3 months.

No complications:

No complications were reported in any of the cases with a follow up time ranging from 8 to 20 months.

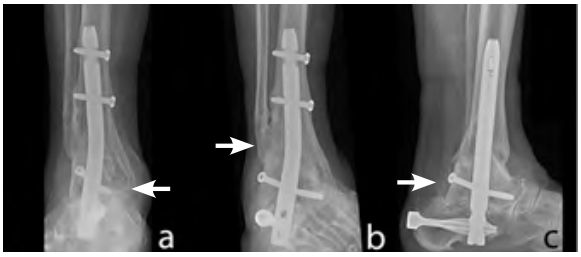
Effective approach for foot and ankle:

The clinical outcomes from this study support ViviGen as an effective approach for achieving fusion in four types of foot and ankle procedures.

Preoperative and postoperative radiographs showing complete fusion

Preoperative

Left: (A) Preoperative anterior-posterior, (B) mortise, and lateral (C) weight bearing ankle radiographs demonstrating end-stage ankle, subtalar and midtarsal degenerative joint disease, secondary to complex clubfoot deformity and subsequent surgeries.



20 months Postoperative

Right: (A) postoperative 20-month anterior-posterior, (B) mortise, and lateral (C) weight bearing ankle radiographs demonstrating complete osseous bridging across the ankle and subtalar joint arthrodesis sites as well as mature osseous integration of the fibula against the tibia, talus and calcaneus.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

68-20-281.01

ARTICLE IN REVIEW:

Salvage of a failed ankle arthroplasty using ViviGen®

PUBLICATION: Clinical Research on Foot and Ankle, December 2018

TITLE: Use of Living Cellular Bone Matrix for Treating a Failed Ankle Arthroplasty: An Abbreviated Technique and Case Study

AUTHORS: Roukis TS.

STUDY DESIGN: Case report

RESULTS: In this case study, a 73-year-old female presented with failure of two previous total ankle replacement procedures. The patient had multiple comorbidities, including obesity, pulmonary hypertension, chronic obstructive pulmonary disease (COPD), and a history of tobacco use. The patient was in significant pain, with a VAS score of 10. An arthrodesis salvage procedure was performed 18 months after the failed revision procedure. Ten cc of ViviGen, in combination with a femoral head allograft, were implanted into the defect site. Fusion was achieved by 12 weeks post-operative, and the patient was weight bearing by 5 months post-operative. The patient was satisfied with the outcomes and reported significant improvements in her pain. This study demonstrates the successful salvage of a twice-failed total ankle arthroplasty using ViviGen.

Fusion achieved by 12 weeks:

The allograft implants — ViviGen Cellular Bone Matrix and a femoral head graft — were fused to the native talus and calcaneus by 12 weeks and to the native tibia by 6 months post-operative.

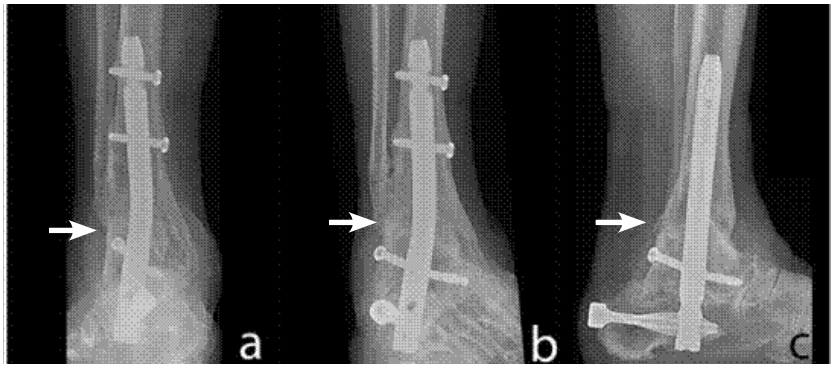
Pain reduction and patient satisfaction:

Significant improvements in pre-operative pain, with a reduced VAS score to 0 in the hindfoot/ankle. Patient was weight-bearing at 5 months post-operative and completely satisfied with the outcomes as of the last follow-up at 23 months post-operative.

Salvage of failed ankle arthroplasty using ViviGen:

ViviGen, combined with a femoral head allograft, enabled successful salvage of a twice-failed ankle arthroplasty.

Complete fusion achieved at 23 months post-operative



23-month post-operative anterior-posterior (A) mortise (B) and lateral (C) weight-bearing ankle radiographs demonstrating mature osseous union of the femoral head allograft to the adjacent tibia, medial malleolus, calcaneus and talar remnant (arrows).

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ARTICLE IN REVIEW:

Explant histology following ViviGen Formable® implantation

PUBLICATION: Journal of Orthopaedic Surgery and Research, January 2020

TITLE: Clinical outcome and explant histology after using a cellular bone allograft in two-stage total hip arthroplasty

AUTHORS: Shahrdar C, McLean J, Gianulis E, Softic D, Qin X, Moore MA, Chen J.

STUDY DESIGN: Case report

RESULTS: Two patients underwent two-stage total hip arthroplasty (THA). ViviGen Formable was implanted at stage 1 to fill bone voids. A small portion of ViviGen was explanted at stage 2 to make room for the hip implant. Patient #1 was a healthy 48-year-old male with advanced osteoarthritis and a history of a femur fracture. Seven weeks after ViviGen implantation, he underwent the second stage of THA. Patient #2 was a 64-year-old female with type 1 diabetes, a history of pelvis fracture, and severe osteoporosis. Second stage of THA was performed 12 weeks after implantation. Neither patient experienced complications. Both demonstrated improved Harris Hip Scores post-operatively. Histological evaluation revealed extensive new bone formation in each explant. New bone formation in patient #2 was less mature than in patient #1, but still effective to support the new implant. These cases position ViviGen Formable as an alternative to autograft even in patients with multiple comorbidities.

New bone formation at 7 weeks:

Explants collected at 7 weeks from patient #1 displayed signs of new bone formation around the ViviGen® bone chips and between the demineralized bone fibers.

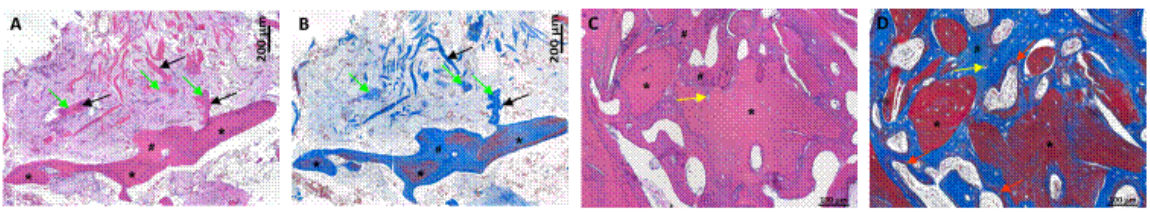
Early and rapid bone formation:

Over 100 µm of new bone was observed in several areas at week 7 in patient #1, which suggests direct participation in bone formation soon after implantation.

Achieved healing despite comorbidities:

Patient #2 had serious comorbidities which can slow new bone formation. While less extensive than patient #1 at week 7, the level of osteoid formation observed at week 12 was enough to help support the implant.

New bone formation in femoral explant from patient 1 at 7 weeks



H&E (A and C) or Masson's trichrome staining (B and D). Newly formed, collagen matrix (# and green arrows) was observed surrounding the implanted ViviGen Formable bone chips (*), as well as between the demineralized bone fibers (black arrows). New mineralization formed within the newly formed bone (red arrows, panel D). Yellow arrows indicate cells surrounded by matrix. Panels A&B: 10x; Panels C&D 20x.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

68-20-289.02

Surgical Repair of Open Femur Fracture with Bone Loss Using ViviGen® Cellular Bone Matrix

CASE STUDY

K Apostle, MD, New Westminster, BC, Canada

The infrequent occurrence of open femur fractures with bone loss has made standardizing treatment difficult.[1] The uncertain outcomes, technically difficult procedures and extensive patient burdens add to the challenge of this surgical repair.[2] One bone-grafting option for managing fractures is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion; however, the retrieval of the autograft can cause pain and site morbidity to patients.[3] The use of allografts can avoid these downsides and one particular allograft, ViviGen, provides all three properties using viable lineage-committed bone cells. ViviGen contains viable cortico-cancellous bone matrix, cortico-cancellous chips, and demineralized bone. Preclinical studies involving seeding of porous ceramic scaffolds have suggested that bone cells may provide a higher degree of bone deposition than mesenchymal stem cells (MSCs).[4,5] Such findings may have relevance in cases where bone fusion has presented a unique challenge.

The following describes the use of ViviGen to treat a challenging open femur fracture case:

Patient

- A 19 year-old patient
- Involved in a motorcycle accident
- Presented with an open, midshaft, left femur fracture with bone loss (Fig 1)
- Previously underwent irrigation debridement and primary wound closure and stabilization with an intramedullary nail for initial fracture management (Fig 2)

Procedure

- At six months following the accident (Fig 3), bone graft from the ipsolateral femur taken using the Reamer/Irrigator/Aspirator (RIA) technique, (DePuy Synthes, West Chester, PA) and 10 cc of ViviGen (LifeNet Health, Virginia Beach, VA) (Fig 4)

Results

- Fusion was achieved within 14 months post-operative (Figs 5-7)

Conclusion

- Patient was satisfied and no complications were observed
- Repair of an open femur fracture using ViviGen was successful at inducing fusion within 14 months

Figure 1.
Presenting films showing an open comminuted midshaft femur fracture

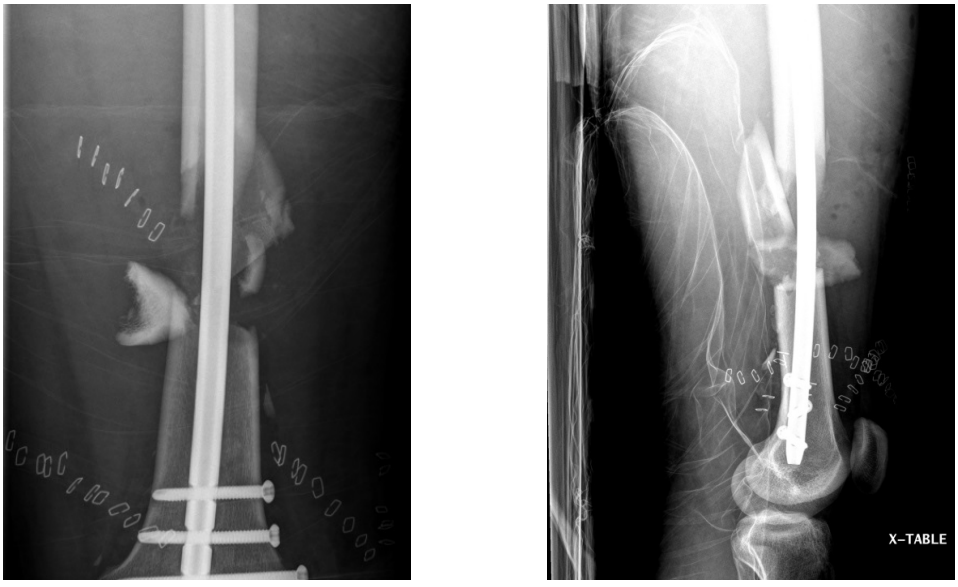


Figure 2.
Post-operative irrigation and debridement, intramedullary nail and primary closure of open wounds was undertaken

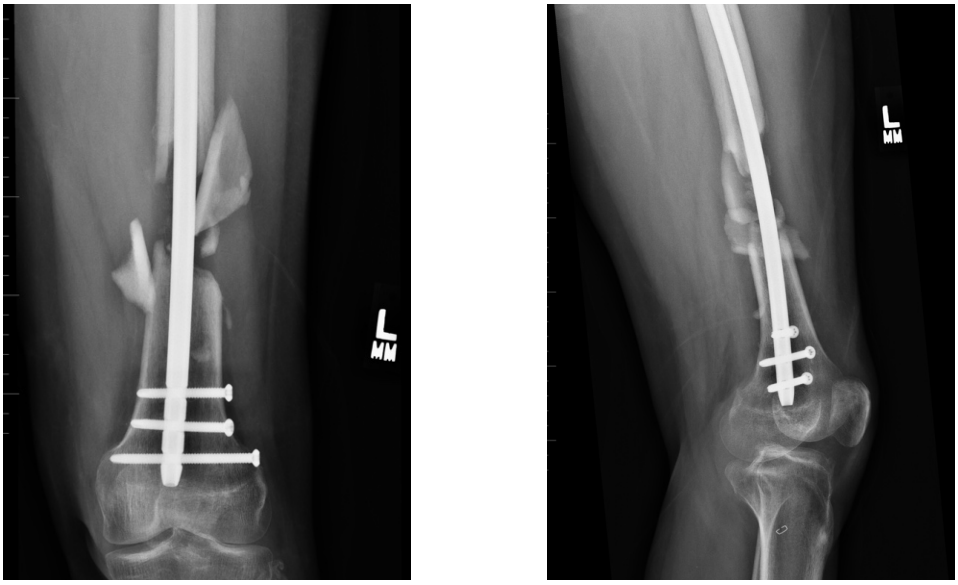


Figure 3.
No visible callous formation and ongoing pain at fracture site six months after initial surgery

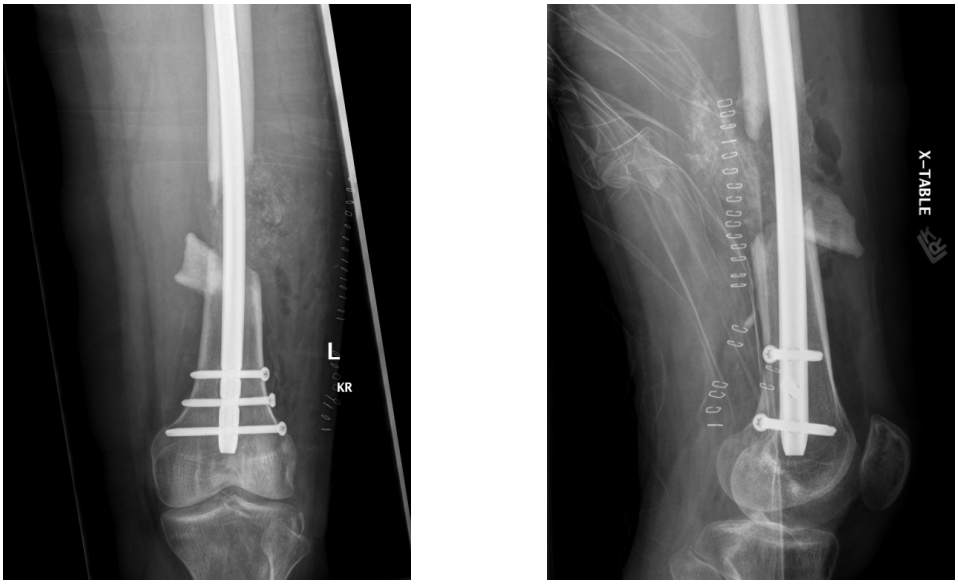


Figure 4.
Images one day following revision surgery using femoral nail, RIA bone graft femur, 10 cc ViviGen

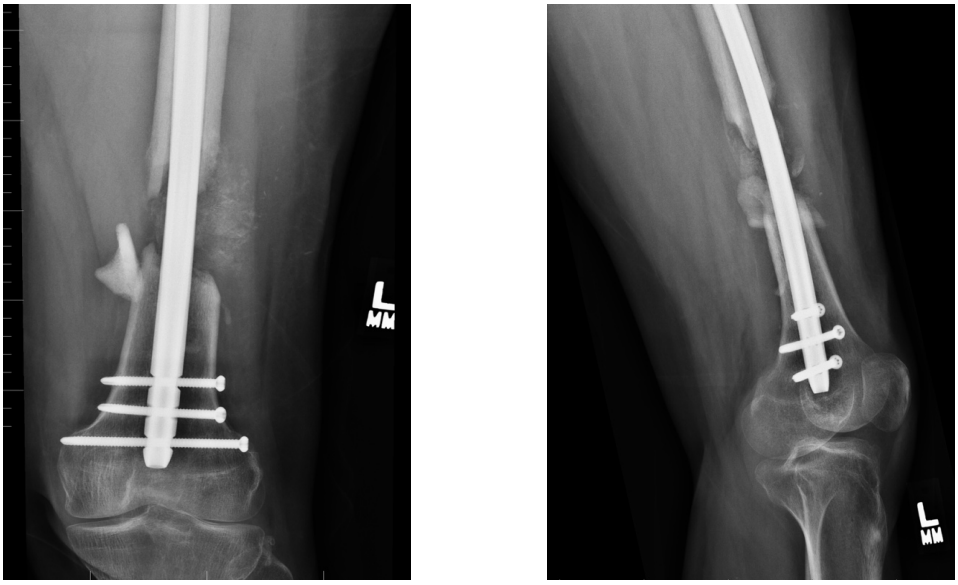


Figure 5.
Images taken six weeks post-operative

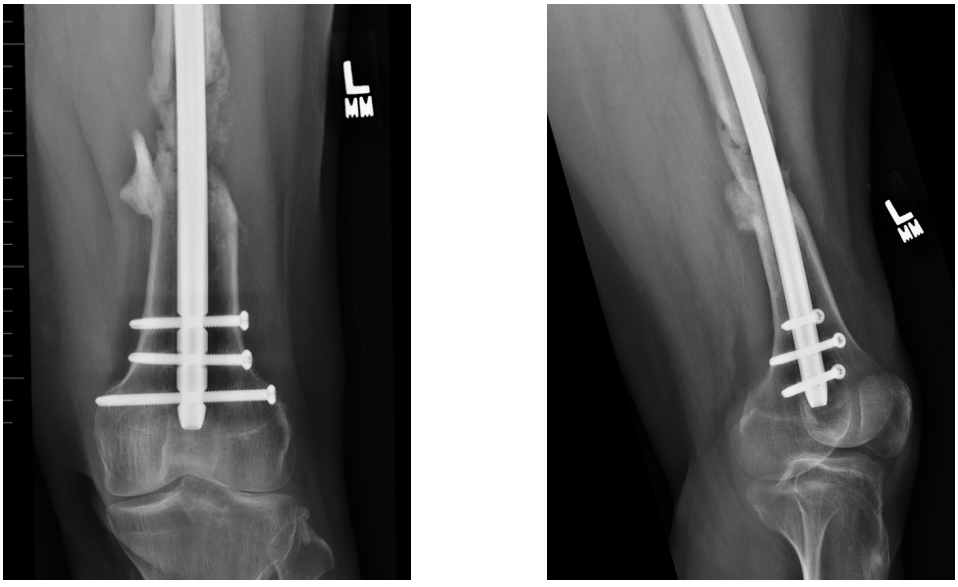


Figure 6.
Images taken six months post-operative

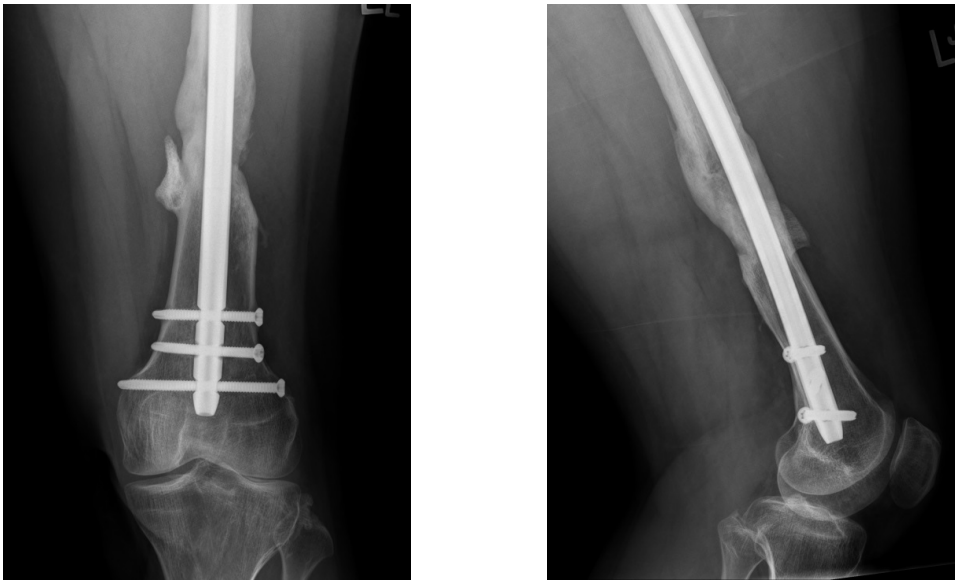


Figure 7.
Fusion observed in radiographs taken 14 months post-operative

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

References

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Surgical Repair of a Tibial Metaphyseal Defect Using ViviGen Formable® Cellular Bone Matrix

CASE STUDY

Ari Kaz, MD; Chicago, IL, USA

Pilon fractures typically occur due to high-energy trauma and cause the comminuted metaphyseal bone to collide against the tibial articular surface.[1] Metaphyseal bone defects, which remain after the stabilization of the fractures, can pose a challenge for treatment.[2] One bone-grafting option for fusing defects is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion; however, its retrieval can cause pain and morbidity at the harvest site.[3] Even in cases in which autograft is desired, there is a limit to the volume that can be harvested without compromising the donor site. Allograft bone can be used as an autograft extender or even eliminate the need for a second surgery site altogether. One particular allograft, ViviGen®, also provides all three properties necessary for bone fusion. ViviGen contains viable lineage-committed bone cells embedded in cortico-cancellous chips as well as demineralized bone particles or fibers. Preclinical studies involving porous ceramic scaffolds seeded with either osteoblasts or mesenchymal stem cells (MSCs) have suggested that bone cells may provide a higher degree of bone deposition than MSCs.[4,5] Findings from these studies suggest that viable bone allografts may have greater relevance in cases where bone fusion is anticipated to be challenging.

The following describes the use of ViviGen Formable to treat challenging tibial metaphyseal defect in a pilon fracture.

Patient

54-year-old, poorly controlled non-insulin-dependent, diabetic male.

Fell five feet off a ladder at work and sustained bilateral displaced pilon fractures. The patient was placed into spanning external fixators on the day of injury. The right side was amenable to open reduction and internal fixation (ORIF). The left side sustained significant swelling, comminution, displacement, and bone loss, which precluded primary ORIF (Figure 1).

Procedure

A circular external fixator was placed with limited ORIF to reduce the talus and tibia (Figure 2). The fixator also allowed for bone stock and alignment for an ankle fusion in the future, while minimizing soft tissue trauma. The metaphyseal bone void was filled with 15 cc of ViviGen Formable (the graft is visible medially), where the handling characteristics allow for ViviGen Formable to be formed and placed with ease.

Results

The external fixator was removed four months post-operative, with radiographs and a CT scan showing consolidation of metaphyseal ViviGen Formable bone graft (Figure 3).

Conclusion

This case highlights the use of ViviGen Formable as a bone graft to fill a metaphyseal defect in a pilon fracture.

Figure 1.
Radiograph and CT images showed the significant swelling, comminution, displacement, and bone loss of the left ankle and tibia.

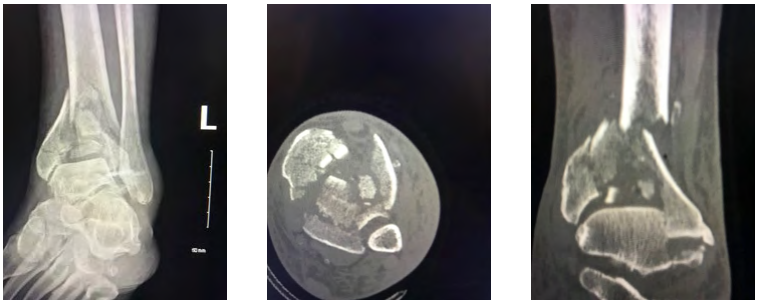

Figure 2.
A circular external fixator was placed with limited ORIF to reduce the talus and tibia.

Figure 3.
Radiograph and CT images showed consolidation of metaphyseal ViviGen Formable bone graft at four months post-operative.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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Surgical Repair of Tibial and Fibular Metaphyseal Defects in Pilon Fractures Using ViviGen® Cellular Bone Matrix

CASE STUDY

Ari Kaz, MD; Chicago, IL, USA

Pilon fractures typically occur due to high-energy trauma and cause the comminuted metaphyseal bone to collide against the tibial articular surface.[1] Metaphyseal bone defects, which remain after the stabilization of the fractures, can pose a challenge for treatment.[2] One bone-grafting option for fusing defects is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion; however, its retrieval can cause pain and morbidity at the harvest site.[3] Even in cases in which autograft is desired, there is a limit to the volume that can be harvested without compromising the donor site. Allograft bone can be used as an autograft extender or even eliminate the need for a second surgery site altogether. One particular allograft, ViviGen, also provides all three properties necessary for bone fusion. ViviGen contains viable lineage-committed bone cells embedded in cortico-cancellous chips as well as demineralized bone particles or fibers. Preclinical studies involving porous ceramic scaffolds seeded with either osteoblasts or mesenchymal stem cells (MSCs) have suggested that bone cells may provide a higher degree of bone deposition than MSCs.[4,5] Findings from these studies suggest that viable bone allografts may have greater relevance in cases where bone fusion is anticipated to be challenging.

The following describes the use of ViviGen to treat challenging tibial and fibular metaphyseal defects in nonunion, pilon fractures.

Patient

31-year-old, healthy, smoker, female

Patient sustained a Grade 3A open fracture on the left distal tibia with an associated distal fibula fracture.

She was treated with emergent incision and drainage (I & D), along with external fixation, with repeat (I & D) five days later. She was placed on intravenous antibiotics for six weeks, and presented to the office three and a half months after her injury. At the initial visit, she had a well-healed 7 cm oblique wound over her medial malleolus, and clean external fixator pin sites. X-rays (Figure 1) showed a reasonably well aligned distal tibia fracture and associated fibula fracture, with obvious osteopenia and metaphyseal bone loss. On the lateral view, there was apex anterior angulation of the fracture. A pre-operative CT scan (Figure 2) showed just a shell of cortical bone and a significant metaphyseal void.

Procedure

The patient's external fixator was removed, and the fractures were opened and debrided. The tibial and fibular metaphyseal defects were filled using 15 cc of autograft and 5 cc of ViviGen, respectively. The fractures were then reduced and open reduction and internal fixation (ORIF) was performed.

Results

At seven months post-operative, the fractures had healed, and the patient was able to return to full activity with no pain or limp (Figure 3).

Conclusion

This case highlights the successful use of ViviGen as a bone graft to fill metaphyseal defects in nonunion, pilon fractures.

Figure 1.
Anterior-posterior radiographs demonstrated a nonunion following open reduction external fixation of the radial shaft fracture.

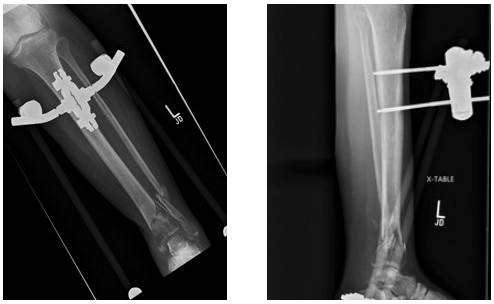


Figure 2.
A pre-operative CT scan showed just a shell of cortical bone and a significant metaphyseal void.

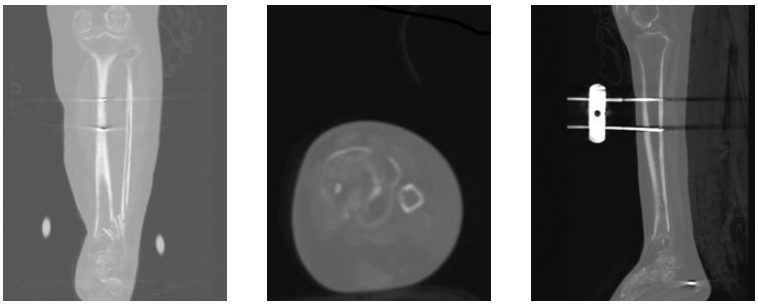
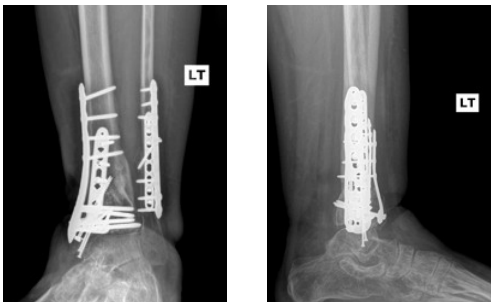


Figure 3.
At 7 months post-operative, the fractures had healed, and the patient was able to return to full activity with no pain or limp



Results from case studies are not predictive of results in other cases. Results in other cases may vary.

References

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68-20-225.00

Surgical Repair of a Nonunion Fracture at the Fifth Metatarsal Using ViviGen® Cellular Bone Matrix

CASE STUDY

Ari Kaz, MD; Chicago, IL, USA

Fractures at the fifth metatarsal can cause pain and difficulty walking.[1] While conservative treatments can be attempted, operative treatments should be considered if nonunion occurs.[2] One bone grafting option for fusing fractures is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion; however, its retrieval can cause pain and morbidity at the harvest site.[3] Even in cases in which autograft is desired, there is a limit to the amount that can be harvested without compromising the donor site. Allograft bone can be used as an autograft extender or even eliminate the need for a second surgery site altogether. One particular allograft, ViviGen, also provides all three properties necessary for bone fusion. ViviGen contains viable lineage-committed bone cells embedded in cortico-cancellous chips as well as demineralized bone particles or fibers. Preclinical studies involving porous ceramic scaffolds seeded with either osteoblasts or mesenchymal stem cells (MSCs) have suggested that bone cells may provide a higher degree of bone deposition than MSCs.[4,5] Findings from these studies suggest that viable bone allografts may have greater relevance in cases where bone fusion is anticipated to be challenging.

The following describes the use of ViviGen to treat a challenging nonunion fracture at the fifth metatarsal.

Patient

34-year-old, smoker, female with a vitamin D deficiency.

Sustained a closed, minimally displaced base fracture of the fifth metatarsal. X-rays (Figure 1) and a CT scan demonstrated no evidence of healing (Figure 2) six weeks after injury.

Procedure

Due to persistent pain and radiographic confirmation of nonunion, surgery was performed, consisting of nonunion takedown, open reduction and internal fixation (ORIF), and bone grafting with 1 cc of ViviGen.

Results

Fusion was confirmed at four months post-operative (Figures 3 & 4).

Conclusion

This case highlights the successful use of ViviGen as a bone graft in treatment of a nonunion, fifth metatarsal fracture.

Figure 1.
X-rays demonstrated no evidence of healing six weeks after injury.

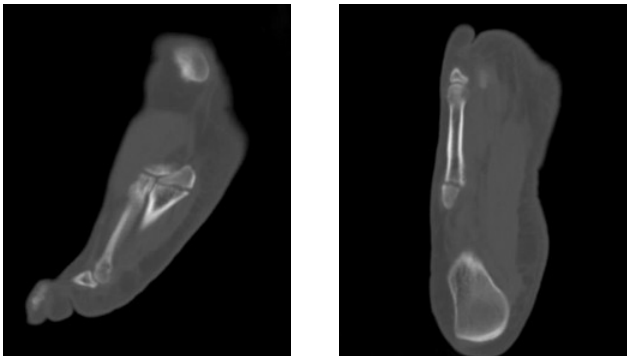

Figure 2.
A CT scan demonstrated no evidence of healing six weeks after injury.

Figure 3.
X-ray images confirmed fusion at four months post-operative.

Figure 4.
A CT scan confirmed fusion at four months post-operative.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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105086-190109 DSUS
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Surgical Repair of a Delayed Union to the Radius Diaphysis Using ViviGen® Cellular Bone Matrix in a Division I Football Athlete

CASE STUDY

W Geissler, MD; Jackson, MS, USA

Delayed union to the radius diaphysis is a challenging injury to treat.[1] High-level athletes face additional obstacles to fracture healing due to their accelerated return to high impact activities.[2] One bone-grafting option for fusing fractures is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion; however, its retrieval can cause pain and morbidity at the harvest site.[3] The use of allografts can avoid these downsides. One particular allograft, ViviGen, also provides all three properties necessary for bone fusion.

ViviGen contains viable lineage-committed bone cells embedded in cortico-cancellous chips as well as demineralized bone particles or fibers. Preclinical studies involving porous ceramic scaffolds seeded with either osteoblasts or mesenchymal stem cells (MSCs) have suggested that bone cells may provide a higher degree of bone deposition than MSCs.[4,5] Such findings may have relevance in cases where bone fusion has presented a unique challenge.

The following describes the use of ViviGen to treat a challenging delayed union to the radius diaphysis case.

Patient

A 22 year old, male, defensive back for a major football program had previously sustained a fracture to the shaft of the radius.

He underwent open reduction internal fixation with a 7-hole 3.5 mm dynamic compression plate. The patient was allowed to return to weight lifting at approximately three months from surgery. While weight lifting, the patient had sudden pain to the forearm.

Radiographs taken at the time showed a delayed union to the radius and the previously applied plate to be bent (Figs. 1, 2). The patient was referred from an outside institution for further management of delayed union of the radial shaft with a bent plate (Fig. 3).

Procedure

The patient was brought back to surgery approximately three months from the original injury and underwent open reduction internal fixation of the radial shaft plate, placing a longer 3.5 mm anatomical forearm plate and 1 cc of ViviGen. Close attention was made to place ViviGen on the radial side of the radius fraction, and not the ulnar side to prevent potential cross union between the radius and ulna (Figs. 4, 5).

Results

Radiographs at the 2 month mark show no loosening of the plate and early bone formation where ViviGen graft was placed (Fig. 6). Radiographs at six months show solid union of the radial shaft, with excellent bone formation across the fracture site (Figs. 7, 8).

Conclusion

The patient was cleared to play in the upcoming 2018 football season without any restrictions and cleared back to weight lifting without any limits. Treatment using ViviGen successfully induced fusion within six months in this high-level athlete.

Figure 1.
Anterior-posterior radiograph demonstrated a delayed union following open reduction internal fixation of the radial shaft fracture.

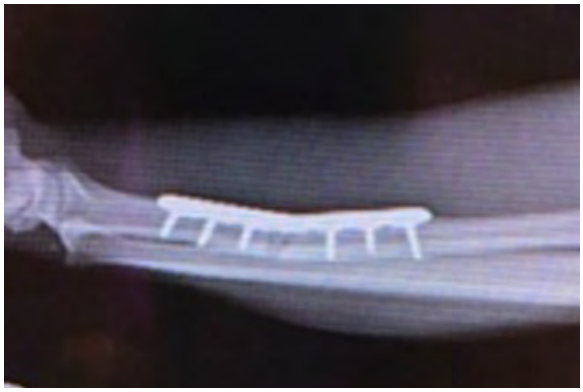

Figure 2.
Lateral radiograph of the same patient approximately 3 months out demonstrated the delayed union of the radial shaft fracture with a bent plate.

Figure 3.
Photograph of the bent stainless steel plate following removal as seen laterally.

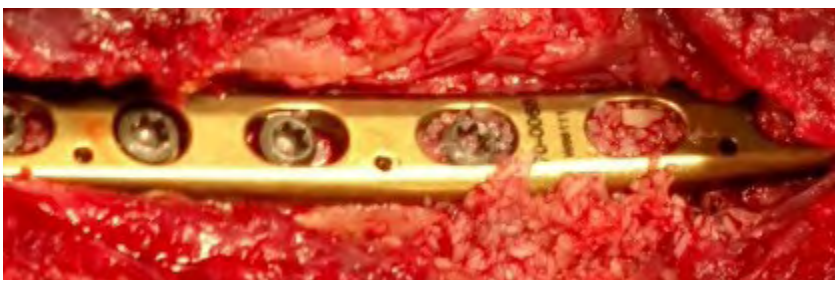

Figure 4.
Intraoperative photograph demonstrating revision of the delayed union of the radial forearm fracture and ViviGen graft being placed primarily on the radial side of the delayed union site.

Figure 5.
Lateral intraoperative fluoroscopic view demonstrating the forearm plate with good compression at the delayed union site.

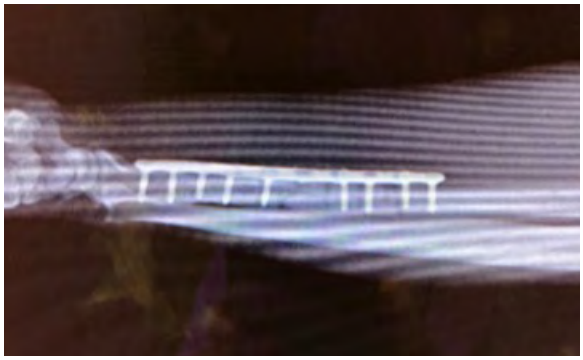

Figure 6.
Lateral radiograph at approximately two months demonstrating no loosening of the hardware and early bone consolidation.

Figure 7.
Six month postoperative anterior-posterior radiograph view showing solid healing at the delayed union site. Note the excellent bone formation across the delayed union site following use of ViviGen.

Figure 8.
Lateral radiograph showing excellent consolidation at the delayed union site at six months post operatively. There was no loosening of the hardware.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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Repair of a Comminuted Talar Neck Fracture using ViviGen Formable® Cellular Bone Matrix combined with a SymAlign® Cotton Allograft Wedge

CASE STUDY

Case performed by: Alaa Mansour, DPM, Timothy Howard, DPM;
Indianapolis, IN, USA

Talar neck fractures are uncommon, accounting for <1% of all fractures.[1-3] Such fractures are typically the result of high energy trauma and are characterized by displacement, comminution, and soft tissue injury. The talus plays an important role in normal foot ambulation and has a unique extraosseous vascular supply. If left untreated, talar neck fractures can lead to major complications, such as osteonecrosis and post-traumatic arthritis, and long-term morbidity. Treatment of talar neck fractures while avoiding complications presents a unique challenge to surgeons. Particularly in cases with significant bone loss, such as in comminuted talar neck fractures, bone-grafting is a common treatment choice.

One bone grafting option is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion. However, it is often associated with limitations, including donor-site morbidity and limited quality and supply.[4] An allograft alternative, ViviGen Formable, also provides all three of these properties while avoiding donor-site morbidity. ViviGen Formable is an osteoconductive scaffold that contains viable cells committed to produce bone in concert with osteoinductive signals naturally found in demineralized bone.

Additionally, because the talus serves as a critical link between the leg and foot[1], restoration of its structural integrity is of utmost importance in repairing talar neck fractures. SymAlign Allograft wedges, with unique texturing and high bone density and strength, were designed specifically to resist graft displacement and endure high compressive force, while maintaining deformity correction.[5]

The following describes the use of ViviGen Formable Cellular Bone Matrix along with SymAlign Cotton Allograft wedge to repair a comminuted talar neck fracture.

Patient

46-year-old male.

The patient presented with an injury to his left ankle following a fall from a 12-foot ladder. The patient recalls his foot getting trapped in one of the ladder steps and twisting. Radiographic and computed tomography (CT) imaging revealed a talar neck fracture spanning from medial to lateral with significant comminution and dislocation of the posterior subtalar joint (Figures 1 & 2). The medial talar neck was noted to have a 6-mm void as well as a varus angulation deformity secondary to the comminution (Figure 1A and B). Laterally, there was impingement of the talus against the lateral malleolus, and two large fracture pieces lodged in the subtalar joint that were preventing reduction of the dislocation (Figure 1C and D).

Procedure

Laterally, open reduction internal fixation (ORIF) was performed to reduce the posterior subtalar dislocation, with plate and screw fixation. Medially, a 6.5mm SymAlign Cotton Allograft wedge was used to correct the varus deformity. Subsequently, 1cc of ViviGen Formable was packed around the SymAlign wedge and within the bony void (Figure 3). The allografts were secured in place using plate and screw fixation.

Results

At 6 months post-operative, the talar neck fracture had healed with solid osseous consolidation evident on radiographic images (Figure 4). The patient returned to regular shoe gear and was back to daily activities.

Conclusion

This case demonstrates the successful repair of a comminuted talar neck fracture using a combination of a SymAlign Cotton Allograft wedge with ViviGen Formable Cellular Bone Matrix. The strong compressive strength and unique textured design of SymAlign Allograft wedges facilitated the structural repair of the talus, while resisting migration. Concurrently, the use of ViviGen Formable to fill the bony void caused by the comminuted fracture facilitated healing of the fracture due to its osteoconductive, osteoinductive, and osteogenic characteristics.

Figure 1.
Radiographic imaging of the left foot revealed a talar neck fracture with posterior subtalar joint dislocation. A varus angulation deformity and a 6mm void (white arrow, B) were evident in the medial talar neck (A and B, respectively). Lateral views revealed impingement of the talus against the lateral malleolus (C) and two large bone fragments lodged in the subtalar joint (D, white arrows).

Figure 1.
AP Preoperative

Figure 2.
Lateral Preoperative

Figure 3.
AP Postoperative
At 8 Weeks Post Op

Figure 4.
Lateral Postoperative
At 8 Weeks Post Op

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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092699-180530 DSUS
68-20-206.00

Ankle and Hindfoot Arthrodesis Using ViviGen® Cellular Bone Matrix

CASE STUDY 2

Zachary Ritter, DPM, UPMC Susquehanna, Williamsport, PA

Arthrodesis is used to treat arthritis, deformity, instability, or pain in the ankle and hindfoot. Although this procedure is the most commonly used technique to treat end-stage ankle arthritis, reported success rates vary widely.[1] One bone grafting option for arthrodesis is autograft. Autograft bone can provide the osteoconductive, osteoinductive and osteogenic properties needed for successful bone fusion; however, the retrieval of the autograft can cause pain and site-morbidity to patients.[2] ViviGen provides all three of these properties using viable lineage-committed bone cells. ViviGen contains viable cortico-cancellous bone matrix, cortico-cancellous chips, and demineralized bone and preclinical studies have suggested bone cells might improve fusion over mesenchymal stem cells by providing better bone deposition[3] while remaining in the defect site longer.[4]

The following describes the use of ViviGen to treat a challenging ankle deformity case.

Patient

- A 23 year old obese, Open Reduction Internal Fixation of distal tibial fracture, female patient
- Complained of deformity, pain, and osteoarthritis in right ankle that had been present for six years
- Failed conservative treatments include bracing, physical therapy, orthrosis, and a rocker shoe

Procedure

- Arthrodesis was undertaken to correct a varus deformity (Figs. 1&2)
- Full thickness cartilage loss was observed
- 5 cc of ViviGen was used

Results

- Fusion was achieved by eight weeks
- Preoperative moderate to severe pain decreased to no pain postoperatively
- Patient was full weight bearing at six weeks with a boot and discontinued boot use at eight weeks

Conclusion

- Patient was “very happy” and no complications were observed
- Arthrodesis using ViviGen was successful at inducing fusion within eight weeks (Figs. 3&4)

Figure 1.
AP Preoperative

Figure 2.
Lateral Preoperative

Figure 3.
AP Postoperative
At 8 Weeks Post Op

Figure 4.
Lateral Postoperative
At 8 Weeks Post Op

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

References

1. Yasui Y, Hannon CP, Seow D, Kennedy JG. Ankle arthrodesis: A systematic approach and review of the literature. World J Orthop. 2016;7(11):700-708.
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092700-180530 DSUS
68-20-207.00

Ankle and Hindfoot Arthrodesis Using ViviGen® Cellular Bone Matrix

CASE STUDY 3

Zachary Ritter, DPM, UPMC Susquehanna, Williamsport, PA

Arthrodesis is used to treat arthritis, deformity, instability, or pain in the ankle and hindfoot. Although this procedure is the most commonly used technique to treat end-stage ankle arthritis, reported success rates vary widely.[1] One bone grafting option for arthrodesis is autograft. Autograft bone can provide the osteoconductive, osteoinductive and osteogenic properties needed for successful bone fusion; however, the retrieval of the autograft can cause pain and site-morbidity to patients.[2] ViviGen provides all three of these properties using viable lineage-committed bone cells. ViviGen contains viable cortico-cancellous bone matrix, cortico-cancellous chips, and demineralized bone and preclinical studies have suggested bone cells might improve fusion over mesenchymal stem cells by providing better bone deposition[3] while remaining in the defect site longer.[4]

The following describes the use of ViviGen to treat a challenging ankle deformity case.

Patient

- A 59 year old former smoker, male patient with human leukocyte antigen (HLA) B27
- Complained of pain, progressive deformity, instability, degenerative joint disorder, and ambulatory changes in left ankle that had gradually onset over 15 years
- Failed conservative treatments include orthosis, topical NSAIDS, and arthrocentesis

Procedure

- Ankle primary fusion was undertaken (Figs. 1&2)
- Valgus rotation with marginal spurring of full thickness cartilage loss observed
- 5 cc of ViviGen was used

Results

- Fusion was achieved by seven weeks
- Preoperative moderate pain decreased to an occasional ache post-operatively
- Patient was full weight bearing at four weeks using a boot and discontinued boot use at seven weeks

Conclusion

- Patient was "very pleased with the result" and no complications were observed
- Arthrodesis using ViviGen was successful at inducing fusion within seven weeks (Figs. 3&4)

Figure 1.
AP Preoperative

Figure 2.
Lateral Preoperative

Figure 3.
AP Postoperative
At 8 Weeks Post Op

Figure 4.
Lateral Postoperative
At 8 Weeks Post Op

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

References

1. Yasui Y, Hannon CP, Seow D, Kennedy JG. Ankle arthrodesis: A systematic approach and review of the literature. World J Orthop. 2016;7(11):700-708.
2. Khan WS, Rayan F, Dhinsa BS, Marsh D. An osteoconductive, osteoinductive, and osteogenic tissue-engineered product for trauma and orthopaedic surgery: how far are we? Stem Cells Int. 2012;2012:236231.
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68-20-208.00

Surgical Repair of Severe Varus Ankle Deformity with Osteoarthritis Using ViviGen® Cellular Bone Matrix

CASE STUDY

Ari Kaz, MD; Chicago, IL, USA

Varus ankle deformities can occur due to a variety of musculoskeletal and nervous system disorders.[1] Post-operative complications and poor outcomes have been observed with ankle arthroplasty in patients with severe angular deformity,[2] which suggests fusion may be a better approach. One bone-grafting option for fusion is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion; however, its retrieval can cause pain and morbidity at the harvest site.[3] Even in cases in which autograft is desired, there is a limit to the amount that can be harvested without compromising the donor site. Allograft bone can be used as an autograft extender or even eliminate the need for a second surgery site altogether. One particular allograft, ViviGen, also provides all three properties necessary for bone fusion. ViviGen contains viable lineage-committed bone cells embedded in cortico-cancellous chips combined with demineralized bone particles or fibers. Preclinical studies involving porous ceramic scaffolds seeded with either osteoblasts or mesenchymal stem cells (MSCs) have suggested that bone cells may provide a higher degree of bone deposition than MSCs.[4,5] Findings from these studies suggest that viable bone allografts may have greater relevance in cases where bone fusion is anticipated to be challenging.

The following describes the use of ViviGen to treat a severe varus ankle deformity with osteoarthritis.

Patient

49-year-old male.

Presented with a long-standing history of left ankle pain, instability, and varus deformity. Pre-operative x-rays showed ankle arthritis and significant varus deformity (Figure 1). The patient was otherwise in good health with the exception of taking over-the-counter medication that may increase the risk for developing osteopenia or osteoporosis.

Procedure

An ankle fusion was performed using proximal tibia bone graft and 10 cc of ViviGen as a bone-graft extender.

Results

Solid osseous union was noted approximately four months after surgery (Figure 2), demonstrating the capability of ViviGen as a bone-graft extender in an ankle fusion.

Conclusion

This case highlights the use of ViviGen as a bone graft to treat a severe varus ankle deformity.

Figure 1. Pre-operative x-rays showed ankle arthritis and significant varus deformity.

Figure 2. Solid osseous union was noted approximately four months after surgery.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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4. Reichert JC, Quent VM, Noth U, Hutmacher DW. Ovine cortical osteoblasts outperform bone marrow cells in an ectopic bone assay. J Tissue Eng Regen Med. 2011;5(10):831-844.
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105089-190109 DSUS
68-20-226.00

Salvage of Failed Wrist Arthroplasty Using ViviGen® Cellular Bone Matrix

CASE STUDY

W Geissler, MD; Jackson, MS, USA

As the number of failures associated with wrist arthroplasties increases, a new and reliable approach is needed for successful salvage using arthrodesis.[1] Co-morbidities, such as rheumatoid arthritis, can further increase the risk of complications with this procedure.[2] One option for achieving arthrodesis is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive, and osteogenic properties needed for successful bone fusion; however, its retrieval can cause pain and morbidity at the harvest site.[3] The use of allografts can avoid these downsides. One particular allograft, ViviGen, also provides all three properties necessary for bone fusion. ViviGen contains viable lineage-committed bone cells embedded in cortico-cancellous chips as well as demineralized bone particles or fibers. Preclinical studies involving seeding of porous ceramic scaffolds have suggested that bone cells may provide a higher degree of bone deposition than mesenchymal stem cells (MSCs).[4,5] Such findings may have relevance in cases where bone fusion has presented a unique challenge.

The following describes the use of ViviGen in a challenging salvage of a failed wrist arthroplasty case.

Patient

66-year-old female

Patient with rheumatoid arthritis presented after undergoing two previous total wrist arthroplasties. The initial wrist arthroplasty lasted approximately 12 years, and the second lasted seven years. The patient strongly desired wrist fusion rather than another attempt at a temporary wrist arthroplasty.

Procedure

The previous total arthroplasty was removed (Fig. 1), which left a large bony defect (Fig. 2). While a humeral or femoral head allograft could be placed to fill this bone deficit, successful union using a pre-contoured wrist fusion plate can be obtained with good bone contact. The large bone defect was filled with 10 cc of ViviGen (Figs. 3, 4). A neutral wrist fusion plate was then placed on the dorsal aspect. (Fig. 5) Fluoroscopic view showed excellent bone contact and placement of the ViviGen graft.

Results

Solid healing was achieved approximately three months from surgery. The final radiograph showed no loosening of the implant (Figs. 6, 7).

Conclusion

The patient was asymptomatic and very satisfied with her wrist fusion as compared to another attempt at wrist arthroplasty. Arthrodesis using ViviGen was successful in inducing bone fusion following a failed arthroplasty procedure in an older patient with rheumatoid arthritis.

Figure 1.
Lateral radiograph demonstrating marked instability and loosening of the total wrist arthroplasty implant.

Figure 2.
Intraoperative image showing the extensive bone loss following removal of the total wrist arthroplasty implant.

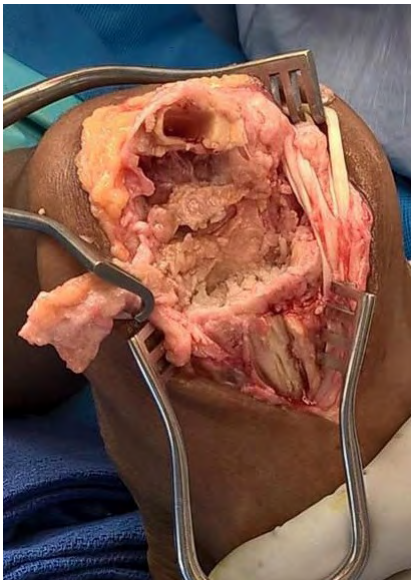

Figure 3.
Intraoperative image showing ViviGen filling the extensive bone defect of the distal carpus.

Figure 4.
Intraoperative image showing ViviGen filling the large defect of the distal radius following removal of the arthroplasty implant.

Figure 5.
Intraoperative image showing excellent bone contact with ViviGen in stabilization with a wrist fusion plate.

Figure 6.
Anterior-posterior radiograph three months post operatively showing excellent alignment of the hand in relation to the forearm with a wrist fusion plate.

Figure 7.
Lateral radiograph at approximately three months postoperative shows excellent fusion at the site with ViviGen. There was no loosening of the implant.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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Mandibular Reconstruction Using ViviGen Formable® Cellular Bone Matrix Following Ameloblastoma Resection

CASE STUDY

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Ameloblastomas are the most common clinically significant odontogenic tumor, characterized by being slow-growing and locally invasive.[1] Ameloblastomas can cause significant morbidity as they expand, and can become quite large without surgical treatment. Rarely, mortality can occur if the tumor envelopes vital structures. Treatment modalities vary from enucleation and curettage to en bloc resection. One bone grafting option following ameloblastoma resection is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive and osteogenic properties needed for successful bone fusion; however, the retrieval of the autograft can cause pain and site-morbidity to patients.[2]

An allograft alternative, ViviGen, also provides all three of these properties while avoiding donor site morbidity. ViviGen is processed from donated human tissue and is intended for repair, replacement or reconstruction of musculoskeletal defects. ViviGen is an osteoconductive scaffold that contains viable cells committed to produce bone in concert with osteoinductive signals naturally found in demineralized bone. Preclinical studies suggest bone cells might improve fusion over mesenchymal stem cells by providing better bone deposition[3] while remaining in the defect site longer.[4]

The following describes the use of ViviGen Formable to reconstruct a mandible following ameloblastoma resection.

Patient

76-year-old female with a history of hypertension, insulin-dependent type 2 diabetes, and GERD.

The patient presented with a lesion in the anterior mandible. One year prior, the patient had a tooth extracted in the area of the lesion, but continued to have multiple local infections with multiple rounds of antibiotics. Radiographic imaging showed a large, radiolucent anterior mandibular lesion (Figure 1). Biopsy confirmed a diagnosis of ameloblastoma.

Procedure

The ameloblastoma was treated with a marginal resection via a transoral approach, packed open and plated using a DePuy Synthes 2.0mm reconstruction plate (Figure 2). A secondary bone graft was planned following healing. Five months later, a secondary reconstruction bone grafting procedure was performed. Due to multiple comorbidities and the patient being a poor surgical candidate for autogenous bone graft harvest, ViviGen Formable was used instead. The resection defect was reopened, debrided of soft tissue ingrowth, and 2cc of ViviGen Formable was placed into the defect (Figure 3) and covered with platelet-rich fibrin membranes from the patient's blood.

Results

The patient did well post-operatively. The hardware was removed at 4.5 months post-implantation. The graft site showed excellent healing with viable bone (Figures 4 & 5). Total treatment time from initial presentation to final healing and hardware removal was 11 months. The patient was functioning well and tolerating an oral diet throughout treatment.

Conclusions

This case demonstrates the successful reconstruction of a mandible using ViviGen Formable following ameloblastoma resection. The mandible was well-healed and stable with viable bone formed at 4.5 months after ViviGen Formable implantation.

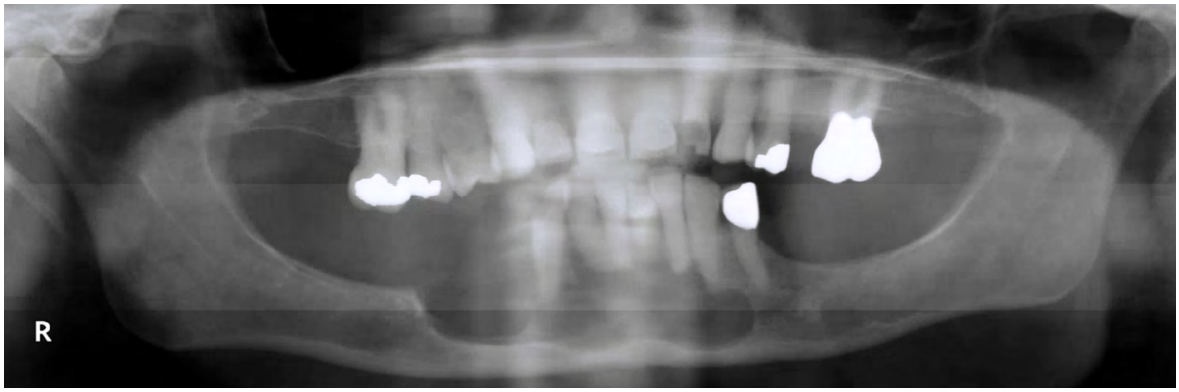

Figure 1.
Initial presentation X-rays showed a large, radiolucent anterior mandibular lesion.

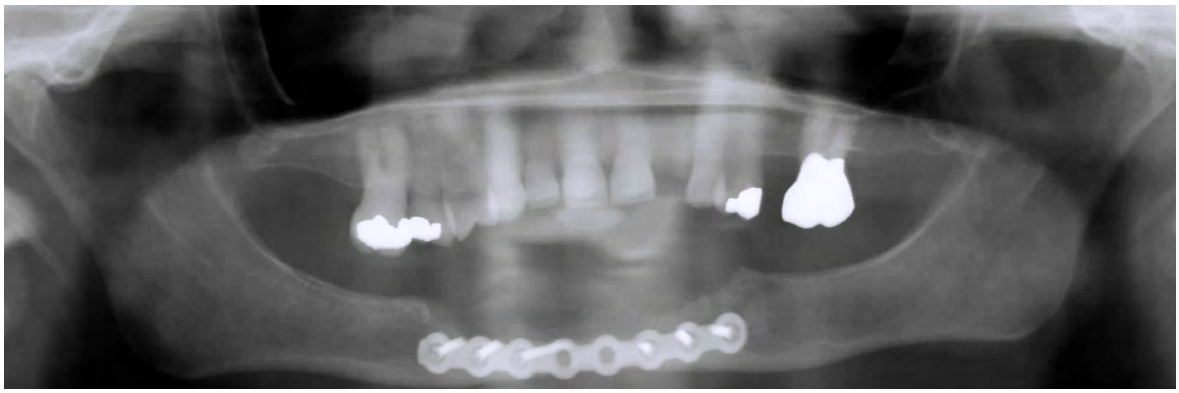

Figure 2.
Initial treatment involved surgical resection of the ameloblastoma, followed by covering the defect site with a reconstruction plate.

Figure 3.
Five months post-resection, images showing defect site before (A) and after (B) ViviGen Formable implantation.

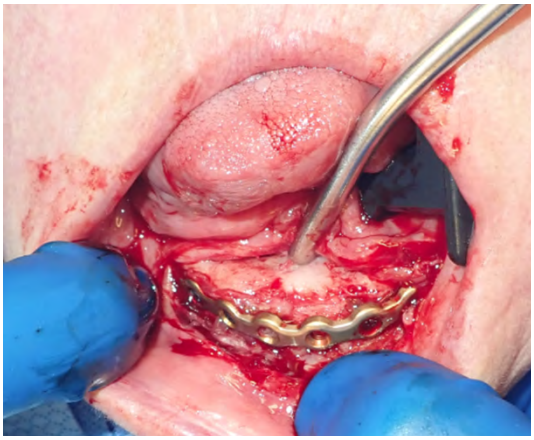

Figure 4.
Image of the graft site 4.5 months after ViviGen Formable implantation showing excellent healing and viable bone formation.

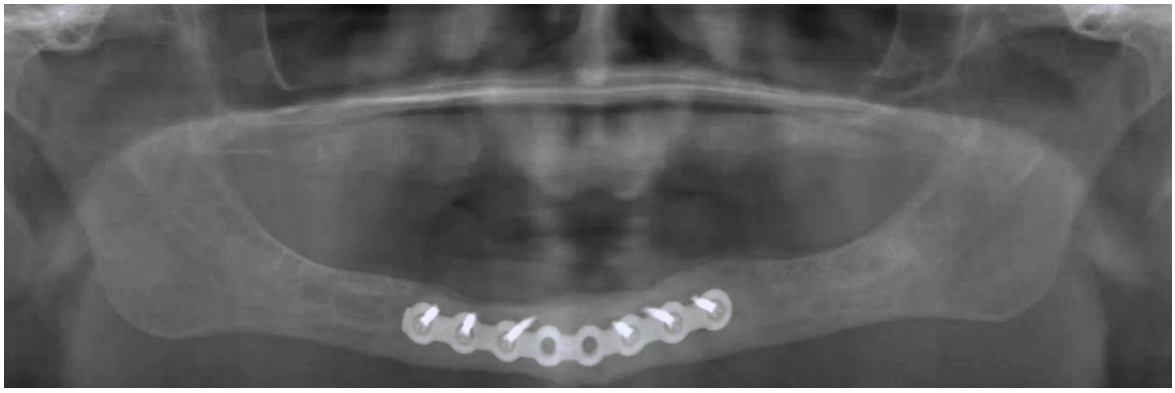

Figure 5.
Radiographic image 4.5 months after ViviGen Formable implantation showing new bone formation at the graft site.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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Surgical Repair of a Mandibular Angle Fracture with Fibrous Union Using ViviGen® Cellular Bone Matrix

CASE STUDY

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Fracture of the mandibular angle is among the most common types of fracture of the mandible (as high as 30%) and is associated with the highest post-operative complication rate.[1,2] Because of this, treatment of mandibular angle fractures presents a challenge to surgeons and remains controversial. One bone-grafting option for managing mandibular angle fractures is autograft bone. Autograft bone can provide the osteoconductive, osteoinductive and osteogenic properties needed for successful bone fusion; however, the retrieval of the autograft can cause pain and donor-site morbidity to patients, as well as increased operative time and cost of the procedure.[3,4] An allograft alternative, ViviGen, also provides all three of these properties while avoiding donor-site morbidity and potentially reducing operative time and cost. ViviGen is processed from donated human tissue and is intended for repair or reconstruction of musculoskeletal defects. ViviGen contains viable lineage-committed bone cells within an osteoconductive scaffold along with osteoinductive demineralized bone matrix. Preclinical studies suggest bone cells improve fusion over mesenchymal stem cells by providing better bone deposition[5] while remaining in the defect site longer.[6]

The following describes the use of ViviGen to treat a mandibular angle fracture with fibrous union.

Patient

- 24-year-old male
- Presented with a right mandibular angle fracture with non-union following trauma to the face.
- Radiographic imaging demonstrated significant malalignment of right mandibular angle fracture with significant continuity defect (Fig. 1). Diagnosis confirmed a fibrous union of the right mandibular angle region.

Procedure

- Debridement and washout of the fibrous union of the right mandibular angle fracture, followed by reconstruction/open reduction internal fixation (ORIF) with a DePuy Synthes Patient Specific Plate Contour (PSPC) reconstruction plate and bicortical screws.
- Tooth #31 was surgically extracted.
- 6cc ViviGen was used to augment and reconstruct the right mandible, followed by maxillomandibular fixation using intermaxillary fixation (IMF) screws and 24 gauge wires.

Results

- Radiographic images demonstrated consolidating ViviGen Cellular Bone Matrix as early as 2 weeks post-operative (Fig. 2) and as long as 6 months post-operative (Figs. 3 & 4).

Conclusion

- Repair of a right mandibular angle fracture with fibrous union using ViviGen was successful in inducing consolidation within 6 months.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

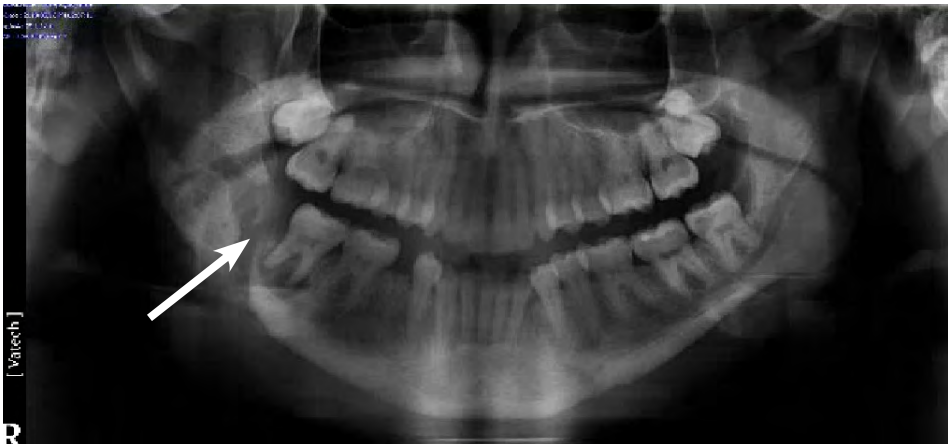

Figure 1.
Pre-operative radiographic image demonstrating significant malalignment of right mandibular angle fracture with significant continuity defect of the mandible in the area of the fracture (indicated by white arrow). Also noted is tooth #31 with periapical radiolucency.

Figure 2.
Radiographic image taken at 2 weeks post-operative showing stable maxillomandibular fixation.

Figure 3.
Radiographic image taken at 3 months post-operative.

Figure 4.
Radiographic image taken at 6 months post-operative demonstrating intact and consolidated bone in the area where ViviGen was implanted (white arrow).

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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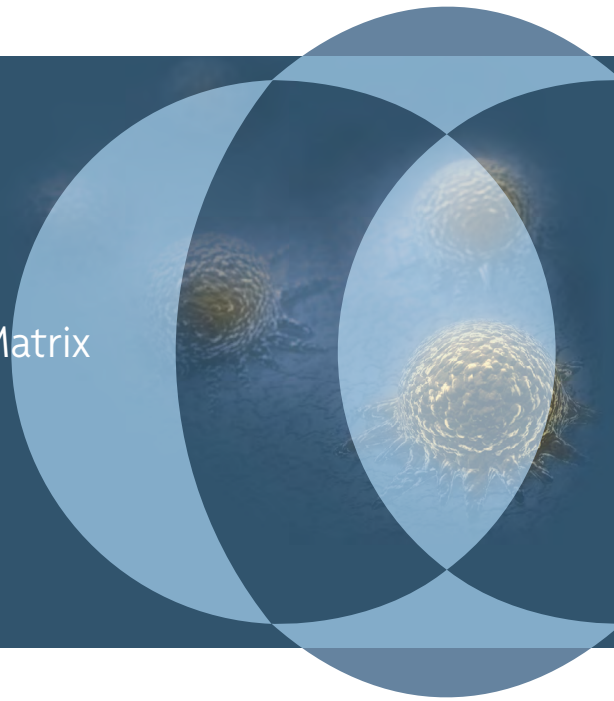
ViviGen®

Cellular Bone Matrix

Clinical Compendium

Use of ViviGen Cellular Bone Matrix in Trauma, Extremity and Craniomaxillofacial Procedures.



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