

ARTICLE IN REVIEW:

ViviGen® demonstrated successful fusion and healing in 86% of 135 high-risk patients undergoing primary and revision foot and ankle procedures

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TITLE: A Retrospective Analysis of Outcomes from Foot and Ankle Arthrodesis and Open Reduction and Internal Fixation using Cellular Bone Allograft Augmentation

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STUDY DESIGN: Retrospective study of 153 consecutive patients, multiple surgeons, single institution

SUMMARY: As of August 2020, this is the largest retrospective case series evaluating the use of ViviGen to achieve successful fusion in ankle/hindfoot/midfoot arthrodesis (n =113) and bony healing in open reduction and internal fixation (ORIF) procedures (n=22) in high-risk patients. Eighteen patients of the 153 total patients were lost to follow-up. Comorbidities included age >65, BMI >30, smoking, diabetes, thyroid disease, Charcot arthropathy, and alcohol abuse. The overall fusion rate in the arthrodesis cohort was 85.84% (97/113) with fusion rates of 83.87%, 85.11%, and 88.68% in the ankle, hindfoot, and midfoot, respectively. Seventy-seven of 90 primary arthrodesis cases had successful fusion (85.56%). Revision cases had a similar rate of fusion at 86.96% (20/23). Smoking and Charcot foot were the only comorbidities to cause a significantly lower rate of fusion (35/46 and 8/13; p=0.01). In the ORIF cohort, the overall rate of successful bony healing was 86.36% (19/22). Primary ORIF cases had a healing rate of 82.35% (14/17), while revision ORIF resulted in 100% (5/5) successful bony healing. There was no statistical difference in healing rates between patients with and without comorbidities (p>0.05). The complication rates in the arthrodesis and ORIF cohorts were 19.5% and 13.6%, respectively, which are considered low compared to reported rates in the literature.^{1,2} These results support the use of ViviGen as an alternative to autograft and MSC-based cellular allografts in arthrodesis and ORIF procedures, particularly for high-risk patients.

Effective despite comorbidities:

ViviGen Cellular Bone Matrix contributed to successful fusion even in patients with comorbidities, such as diabetes, thyroid disease, and/or alcohol abuse, which put them at higher risk for nonunion.^{3,4} In the arthrodesis cohort, only smoking and Charcot foot were associated with a lower rate of fusion. Comorbidities in the ORIF cohort did not compromise bony healing.

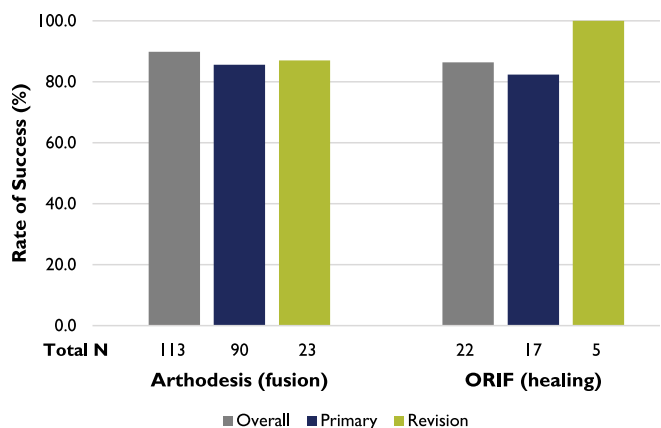
Fusion and healing rates comparable to autograft:

The overall fusion rate in 113 high-risk patients with comorbidities in the arthrodesis cohort was 85.84%. The overall bony healing rate in 22 high-risk patients with comorbidities in the ORIF cohort was 86.36%. These fusion and healing rates are comparable to reported rates using autograft.⁵

No significant difference between primary and revision surgery:

Primary arthrodesis procedures resulted in an 85.56% rate of successful fusion versus 86.96% for revision. Primary ORIF procedures resulted in an 82.35% rate of successful bony healing versus 100% for revision. There was no statistically significant difference between primary and revision surgery (p>0.05). Published literature suggests poorer outcomes following revision surgery.⁶

Fusion and Healing Rates in Arthrodesis and ORIF using ViviGen in High-Risk Patients



Adapted from Table 2.

References:

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3. Zura R, Xiong Z, Einhorn T, et al. Epidemiology of Fracture Nonunion in 18 Human Bones. *JAMA Surg.* 2016;151(11):e162775.
4. Tuchendler D, Bolanowski M. The influence of thyroid dysfunction on bone metabolism. *Thyroid Research.* 2014;7:12.
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6. Lachman JR, Ramos JA, Adams SB, Nunley JA, Easley ME, DeOrio JK. Patient-Reported Outcomes Before and After Primary and Revision Total Ankle Arthroplasty. *Foot Ankle Int.* 2019;40(1):34-41.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

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