

ARTICLE IN REVIEW:

ViviGen® outperformed conventional MSC-based cellular bone allografts in clinical and patient-reported outcomes in ankle arthrodesis procedures

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TITLE: A Retrospective Comparison of Clinical and Patient Reported Outcomes in Foot and Ankle Arthrodesis Procedures Using Two Cellular Bone Allografts

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STUDY DESIGN: Retrospective, comparative study of 47 patients, single surgeon

SUMMARY: Cellular bone allografts (CBAs) are an alternative to autograft for foot and ankle procedures which provide the same bone-forming qualities for successful fusion: osteoconductivity, osteoinductivity, and osteogenicity. Traditional CBAs like Trinity contain adult mesenchymal stem cells (MSCs) which may differentiate into unwanted cell types. ViviGen addresses this risk by containing lineage-committed bone-forming cells. This retrospective study directly compares the use of ViviGen versus Trinity in ankle fusion procedures with or without subtalar fusion. In patients treated with ViviGen (n=31), 100% achieved successful ankle fusion while those treated with Trinity (n=16), had significantly lower fusion (50%; $p<0.0001$). Subtalar joint fusion was comparable between ViviGen (n=28) and Trinity (n=14) patients (89.29% vs. 71.43%, ns). In diabetic patients and tobacco-users, the rate of ankle fusion in each was 100% with ViviGen versus 50% with Trinity. Postoperatively, patients who received ViviGen were more satisfied with their results (100% satisfaction vs 68.75%, $p=0.0028$), demonstrated significantly greater decrease in pain (mean postoperative VAS=1.4 vs 3.15 for Trinity; $p<0.01$), and experienced significantly lower complication rates (6.45% vs 62.5%; $p<0.0001$). In foot and ankle arthrodesis, ViviGen outperformed Trinity and provided greater clinical and patient-reported success while minimizing the risk of complications.

Significantly higher ankle fusion rates:

At 6 months postoperative, the rate of ankle fusion in patients treated with ViviGen Cellular Bone Matrix was double that of patients treated with Trinity (100% vs. 50%; $p<0.0001$).

Effective despite comorbidities:

In diabetic patients and tobacco-users, successful ankle fusion was achieved in 100% of ViviGen patients (9/9 diabetic patients, 5/5 tobacco-users) compared with 50% of Trinity patients (3/6 diabetic patients, 2/4 tobacco-users).

Significantly lower postoperative pain and complications:

Postoperative, patients treated with ViviGen reported significantly greater satisfaction and lower pain (100% vs 68.75% and mean VAS=1.4 vs 3.15; $p<0.01$). The rate of complication in ViviGen was approximately one-tenth that of Trinity (6.45% vs 62.5%; $p<0.0001$). Complications in the ViviGen group were solely due to hardware failure, while those in the Trinity group included hardware failure, nonunion, infection and amputation.

Superior Clinical and Patient-Reported Outcomes with ViviGen

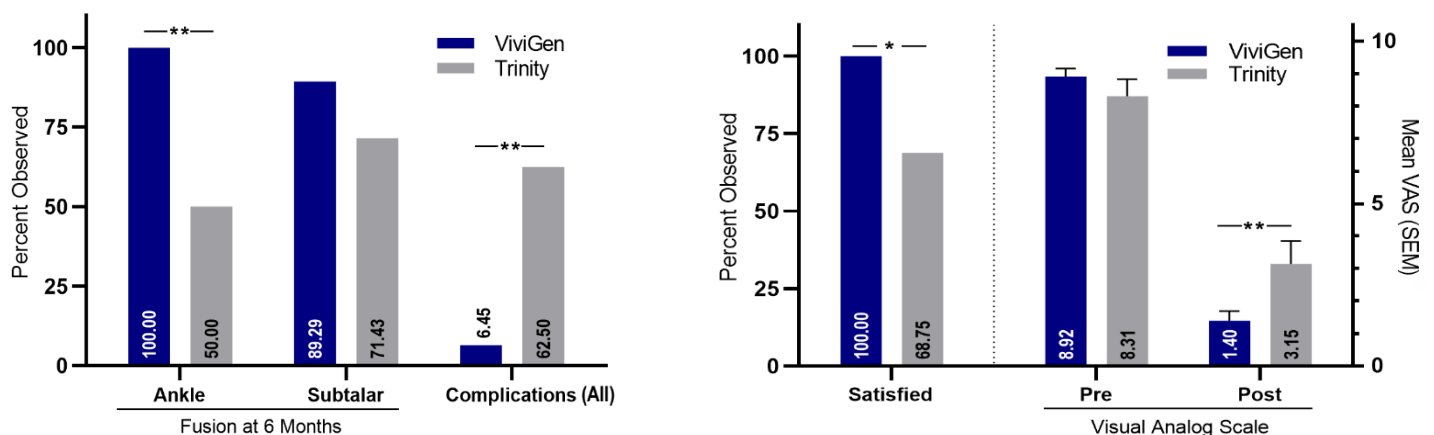


Figure 2 and Figure 3 adapted and reproduced with permission.

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

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