Efficacy of a Cellular Allogeneic Bone Graft in Foot and Ankle Arthrodesis Procedures

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KEYWORDS

• Map3 • Allograft • Arthrodesis • MAPCs • Foot • Ankle • Nonunion • Stem cell

KEY POINTS

- The use of a cellular allogeneic bone graft is safe and effective in foot and ankle arthrodesis patients with risk factors known to cause nonunion.
- Map3 provided an overall fusion rate of 83% in a mostly high-risk population for nonunion.
- The use of this cellular allogeneic bone graft nullified the risk of nonunion for patients with infection, previous nonunion, avascular necrosis, and positive smoking status.
- Diabetes was the only independent risk factor for arthrodesis nonunion, despite the use of Map3 in this patient population.
- Patients with diabetes must be counseled about the risk of nonunion despite the use of supplemental biological therapy for arthrodesis procedures.

INTRODUCTION

Arthrodesis remains the gold standard treatment of end-stage arthritis of the foot and ankle. However, fusion is not guaranteed. Many patients have comorbidities that portend to an increase risk of nonunion, including smoking, diabetes, and avascular necrosis, among others. In various ways, all of these comorbidities compromise vascularity and in turn the delivery of nutrients and host reparative cells to the arthrodesis site. Attempting arthrodesis in these high-risk patients has led to nonunion rates as high as 40%, which can lead to persistent pain and debilitation.[1–4]

In 1965, Urist[5] demonstrated the ability of autologous graft to differentiate and form bone due to bone morphogenetic proteins demonstrating the osteoinductive properties of autograft. Today, autograft is considered the gold standard bone graft as it

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attempts to stimulate local biology at nonunion sites as it provides the essential elements of bone formation: osteoconduction, osteoinduction, and osteogenicity.[6] To increase the union rate, autologous bone graft is used to enhance bone healing at primary arthrodesis and revision nonunion sites. Autologous bone graft is often supplemented even in primary surgical procedures in patients that are at high risk of nonunion with the comorbidities outlined earlier or the presence of a bone void at the arthrodesis site.

However, the incidence of complications and postoperative morbidity after autograft bone harvest has been reported to be as high as 23%.[7] These complications include donor-site pain, infection, fracture, seroma, wound complications, sensory loss, and scarring.[8] In addition, autograft collection is not a viable option for every patient, with limitations associated with the available supply of graft material or variability in the quantity and quality of osteoprogenitor cells present in patients with advanced age or medical comorbidities. Therefore, many attempts have been made to produce allogeneic bone graft supplements with the elements essential for increased bone growth and the avoidance of morbidity of autologous bone graft harvesting.

Allogeneic bone grafts are a viable alternative to avoid the possible complications associated with the collection of autograft bone. This study reports on the use of Map3 (RTI, Alachua, Florida) cellular allogeneic bone graft. The allograft contains cortical cancellous bone chips that serve as an osteoconductive scaffold, demineralized bone matrix (DBM) with verified osteoinductive potential, and viable multipotent adult progenitor-class (MAPC) cells capable of osteogenesis and the production of angiogenic signals to support the bone healing process.

The purpose of this study was to review of use of Map3 cellular allogeneic bone graft in foot and ankle arthrodesis surgeries in patients with risk factors that have been previously shown to increase the rate of nonunion. This study evaluates the clinical effectiveness of Map3 cellular allogeneic bone graft and reports resulting complications in this patient cohort.

METHODS

An Institutional Review Board–approved retrospective chart review was performed at a single academic institution. Patients in this case series underwent foot or ankle arthrodesis that required use of Map3 cellular allogeneic bone graft to fill a bony defect at the time of arthrodesis surgery. In all cases, Map3 was placed in the bony defect between the two intended healing surfaces (prepared joint surfaces). A foot and ankle fellowship-trained orthopedic surgeon with extensive experience in complex ankle and hindfoot reconstruction procedures performed all surgeries.

Clinical records were obtained to determine patient demographics, comorbidities, fixation methods, use of biological adjuvants at the time of surgery, union outcome, and complications. The authors' primary objective was to determine the effectiveness of achieving radiographic union in the setting of patients at risk for nonunion. Fusion was defined by consensus between 2 foot and ankle fellowship-trained investigators after assessing the radiographs and computed tomography (CT) scans when available. Successful radiographic fusion required the presence of bridging bone, no radiographic signs of nonunion, maintenance of fixation across the surgical site as previously defined,[9] and resolution of preoperative symptoms. CT scans were obtained at the treating surgeon's discretion.

Student t-tests were used to assess fusion rates comparing all comorbidities in a univariate analysis. A 2-by-2 contingency table and Fisher exact test of independence were used to compare fusion rates using Map3 alone versus Map3 with additional