# Trabexus®

*Trabecular Osteoinductive Biocement†*

## *Clinical Report*

*Real World Case Series from an Orthopaedic Oncology Practice*

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Vivorté®
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## ABSTRACT

Cavitary bone defects are created following curettage and debridement of benign bone tumors or malignancies. In order to properly heal these bone defects, the resultant voids must be filled with bone graft or substitute material to facilitate bone healing and prevent infiltration of non-osseous fibrous tissue. Due to the inherent drawbacks of autologous bone graft (e.g. supply limitations, variable quality, additional operative time, patient morbidity), synthetic bone graft substitutes have been developed and are available for clinical use. However, despite the availability of a wide array of bone graft substitutes, the quest for an ideal bone graft remains elusive.

The practice of orthopedic oncology creates challenging demands for bone graft substitutes, which must exhibit excellence across a multitude of product performance attributes including mechanical strength and remodeling characteristics, along with possessing adequate intraoperative handling properties. From a biomechanical perspective, an ideal bone graft must have sufficient mechanical strength, equaling or exceeding that of adjacent cancellous bone. Moreover, the material's biomechanical strength should be durable, lasting until new bone is able to form in its place. Given the generally younger patient demographic in orthopedic oncology, the remodeling characteristics of the bone graft substitute are also important. An ideal bone graft should remodel at a rate in concert with the formation of new bone, not resorbing too quickly and creating a new bone void, or resorbing too slowly and serving as an impediment to new bone formation. Lastly, superior intraoperative performance and handling is paramount. An ideal material would have versatile handling properties, permitting material placement manually, or through a minimally invasive technique and be visible during injection under fluoroscopy.

A newly developed bone graft substitute (Trabexus®, Vivorté, Louisville, KY) combining a self-setting calcium phosphate matrix with engineered allograft bone particles encompasses many of the characteristics of an ideal bone graft substitute. The purpose of this review was to evaluate the clinical performance and safety of Trabexus in a cohort of "real world" cases and illuminate the product's suitability in a typical orthopedic oncology practice.

## INTRODUCTION

Trabexus® is a proprietary, biocompatible, gradually resorbable matrix comprised of calcium phosphate and processed allograft particles. Upon mixing, the product components form a self-setting paste that solidifies to a compressive strength of up to 25MPa. This compressive strength is significantly higher than other cements of similar composition.[1] Trabexus can be implanted manually or extruded through a cannula to apply the material in a minimally invasive and controlled manner. Further, Trabexus exhibits high radiopacity, enabling precise placement under fluoroscopy.

A key feature of Trabexus is the thoughtful design of the allograft component. The allograft particles within Trabexus are formed into "hourglass" shapes using a proprietary manufacturing process. The particles are also partially demineralized, exposing osteoinductive factors that can influence and direct bone repair. The novel shape increases the "interconnectivity" of adjacent particles (shown below) while the surface demineralization enhances the remodeling of the allograft component. As a result, the allograft remodels more rapidly than the surrounding cement, creating an extensive network of channels that enhances remodeling of the overall construct.

A. B.

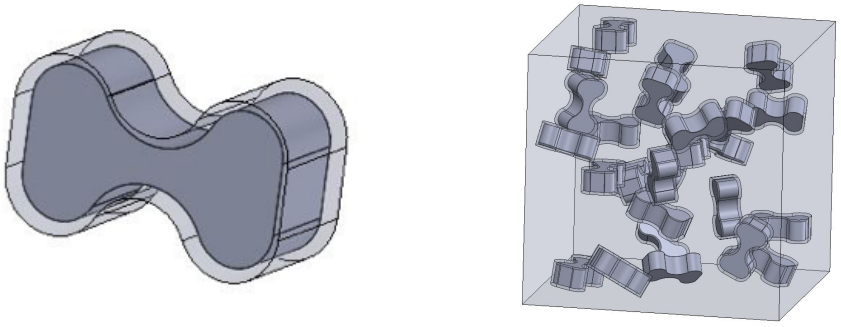

Figure 1. A. Rendering of TRAB™ particle (surface demineralization depicted in light grey). B. TRABS are optimally designed to "interconnect" with adjacent particles within a volume of cement and extend to the boundary of the defect, promoting new bone infiltration.

## MATERIALS & METHODS

Four (4) patients underwent surgery to resect benign tumors or cysts leaving behind bony voids requiring backfilling with bone graft to reduce the incidence of pain and the risk of fracture. In place of autograft, each void was filled with a novel bone substitute (Trabexus®, Vivorté, Louisville, KY) to avoid the increased operative time and patient morbidity associated with harvesting autograft.

Trabexus was prepared in accordance with the product's instructions for use. The contents are enclosed in multi-compartment, sterile, single-use kit convenient for surgical use. The allograft component (i.e. TRABS) are first added to the dry powder and mixed. Then, the liquid component (which contains a setting catalyst solution) is added and mixed for 60 seconds at which time Trabexus is ready for application into the bony defect. As needed, the material can be manipulated for an additional 3.5 minutes of working time.

Trabexus was implanted using a minimally invasive technique using the provided cannula. Following the working time period, the cement begins to harden. Full hardness is typically achieved in 8-10 minutes, however up to 15 minutes of elapsed time may be required depending on individual patient/clinical circumstances.

Setting of Trabexus is isothermic and therefore will not elicit cytotoxic thermal damage to surrounding tissues. Upon setting the ceramic component of Trabexus converts to hydroxyapatite, which is consistent with the mineral phase of normal human bone.[2]

## RESULTS

All patients were surgically treated with curettage and bone grafting. Trabexus was implanted in all cases and demonstrated easy mixing & handling, proper injection/manual placement and solidified quickly, making it compatible with the flow of the surgical environment. Post-operative pain was improved for all patients. The post-operative performance of Trabexus was also excellent, as there was no evidence of an inflammatory response, infection, device migration or any other device-related complication in this series.

Table 1: Summary of Clinical Indications

| Patient | Indication | Location |
|---|---|---|
| 1 | Simple bone cyst | Right proximal femur |
| 2 | Simple bone cyst | Right proximal femur |
| 3 | Chondroblastoma | Right medical talus |
| 4 | Non-ossifying fibroma | Left proximal tibial metaphysis |

## RESULTS

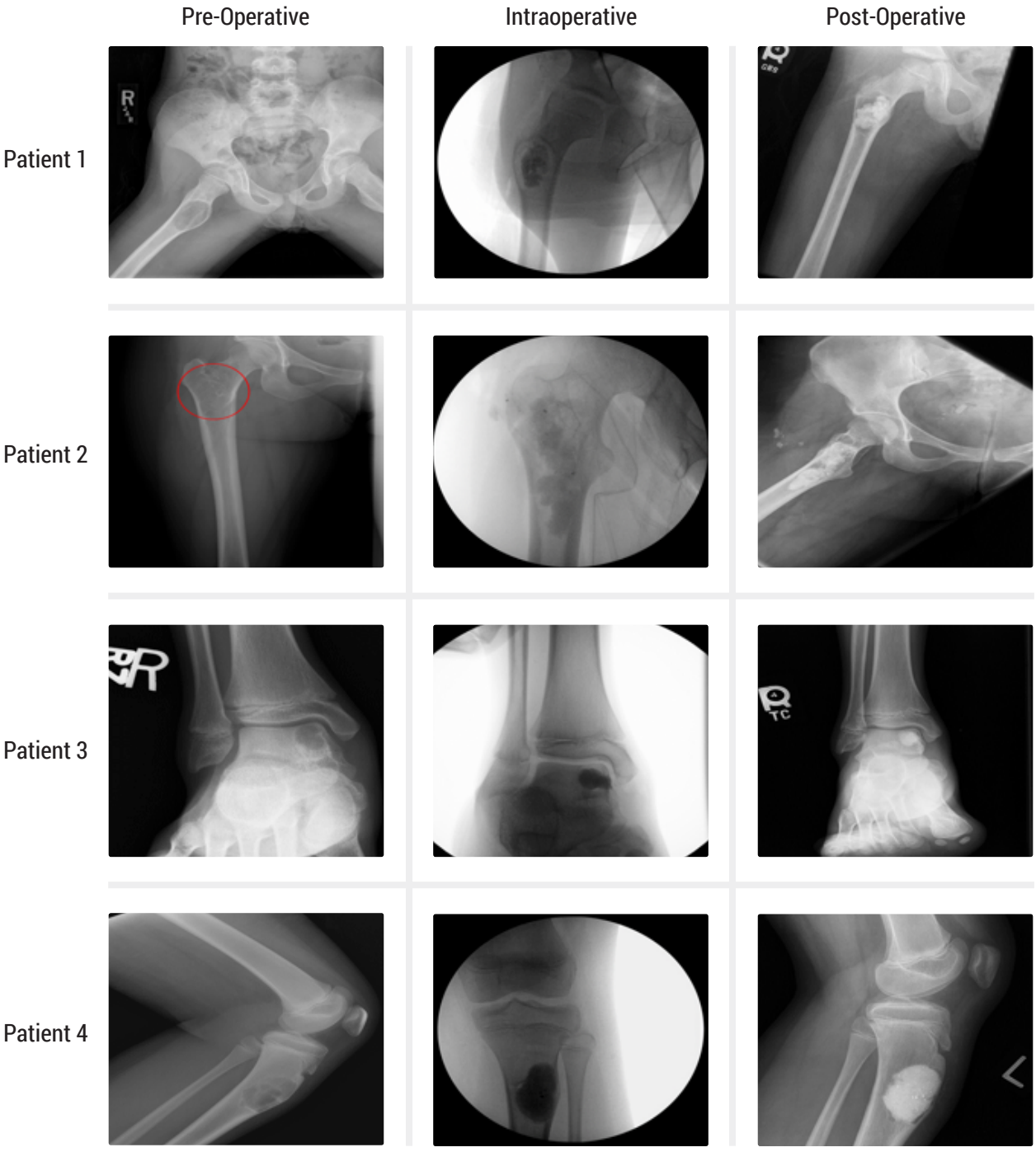


Figure 2. Pre-operative, intraoperative and post-operative imaging was reviewed and demonstrated remodeling over time.

## DISCUSSION

Trabexus demonstrated meaningful clinical utility in this cohort of clinical patients. Trabexus is available off-the-shelf and does not require any special handling, such as cold storage or refrigeration. Preparing the graft is straightforward, and is ready for implantation following 60 seconds of mixing. Due to its composition, Trabexus is highly radiopaque and requires no additional radiopacifiers or contrast agent to ensure visibility under fluoroscopy. Further, the graft may be implanted manually, or extruded through a cannula for precise delivery to the surgical site. Upon implantation, the graft solidifies isothermically, without generating heat that could potentially harm adjacent tissues.[1] Trabexus does not swell or expand during setting[1], a condition that could lead to pressurization of the implant or extravasation of the material outside the intended delivery area. Importantly, Trabexus obviates the need for harvesting autogenous bone graft and thus reduces overall operative time and the potential for post-operative complications.

The ideal bone graft substitute should be stronger than cancellous bone throughout the entire healing process. If at any point in time, the compressive strength drops below that of cancellous bone (~5 MPa)[3] undesired stresses may be imposed and mechanical requirements for these applications may be compromised. Trabexus' optimized formulation of calcium phosphate and partially demineralized allograft results in a solidified construct with a compression strength of up to 25 MPa.[1] Remodeling of Trabexus occurs gradually, at a rate slower than calcium sulfate containing materials, which often resorb more quickly than new bone can form in its place, yet more rapidly than purely synthetic cements that may take years to completely remodel.[4] As designed, Trabexus strikes a unique balance of compressive strength and remodeling rate, distinct from many other products available for use in orthopedic surgery.

To conclude, Trabexus performed well in this small patient series of cases seen within a typical orthopedic oncology practice. Following surgery, patient pain was markedly improved, and there was no inflammatory response, infection or reoperation as a result of Trabexus implantation. The material has attractive handling, intraoperative characteristics and appeared to remodel normally in these patients, without contributing to patient morbidity or post-operative complications. Although further longer follow up is desired to see full resorption in these patients, radiographic imaging and clinical follow up demonstrate the product's safety and effectiveness for use as a novel bone void filler in these applications.

## REFERENCES

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†Allograft component demonstrated osteoinductivity in athymic mouse model submitted in support of 510(k) clearance (K143547)

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