Symphony™ PCS (Platelet Concentrate System) in Tibial Bone Grafting: A Report of Three Cases

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Abstract

Long bone fractures are a major concern for orthopaedic surgeons. Hospitalization estimates for all fractures range as high as 1 million per year in the United States alone.[1] Of these patients with certain long bone fractures, studies indicate that between 5 and 13 percent will need follow-up treatment for nonunion.[2,3]

Although many procedures exist for the treatment of nonunion, skeletal fixation with autogenous bone grafting remains the preferred procedure. However, the limited amount of donor tissue and donor site morbidity impacts its usefulness.

Recently, the use of autologous platelet concentrate (PC) in combination with demineralized bone matrix (DBM) has been studied as a bone graft extender in oral surgery. PC is known to contain locally acting growth factors that effect critical bone repair functions such as cell migration, proliferation, differentiated-function and angiogenesis.[4-6]

This paper describes the author's experience using PC in combination with freeze-dried cancellous allograft bone chips as an alternative to autograft in treating three patients with the following diagnoses: tibial shaft nonunion, proximal tibial malunion and tibial osteomyelitis of the distal tibial metaphysis. The platelet concentrate in each case was prepared using the Symphony™ PCS distributed by DePuy Orthopaedics, Warsaw, IN.

Introduction

The choice of graft material, particularly in nonunions, is based on the need for a structural function, a bone-forming function or a combination of the two. Other considerations for the surgeon would include availability of graft material, quality of the recipient bony bed and costs associated with the procedure. Although direct health care costs are a concern, the physician must also weigh costs to the patient such as lost time from work, pain and a variety of other indirect costs.

Clinically, the use of graft materials and PC to help stimulate bone formation applications has been encouraging.[7] This leads us to ask the question: Would the same process work in orthopaedic applications?

Watson presented a series of six cases with various recalcitrant non-unions of long bone fractures using the Symphony Platelet Concentration System. In all cases the patients were shown to be clinically healed, pain free and had normal functionality restored.[8]

Lowrey, et al. studied 19 patients who underwent spinal fusion using autologous growth factor from an ultraconcentration of platelets. Solid fusion was confirmed in three patients having routine hardware removal and in two patients undergoing surgery at an adjacent level. In the remaining 14 patients, radiographs taken at their last follow-up confirmed fusion. In all cases there was no radiological or clinical evidence of pseudoarthrosis.[9]

PC has also been found useful in avoiding certain complications of total knee arthroplasty (TKA). Mooar and colleagues studied the results of 85 TKAs performed by two surgeons. PC was applied to the cut bone surfaces, synovium and lining of the wound at closure. Patients receiving PC required less IV and oral narcotics, achieved higher functional range of motion and had less drop in Hgb when compared to controls.[10]

The patient's own blood contains an abundance of the growth factors that are necessary for the initiation and propagation of fracture healing. Growth factors such as Platelet-derived Growth Factor (PDGF), Transforming Growth Factor-Beta (TGF-Beta), Epidermal Growth Factor (EGF) and Vascular Endothelial Growth Factor (VEGF) are derived from platelets. Symphony PCS captures platelets from whole blood and concentrates them yielding three to six times baseline levels. Growth factors found in the platelets are thereby increased three to six times baseline levels as well.[11]

Methods and Materials

Symphony PCS provides a simple and automatic process for preparation of a platelet concentrate. Using this system, PC can be prepared in less than 15 minutes and requires as little as 55mL of blood. The system is designed for use within the operating room at point-of-care.

For the cases discussed in this report, PC material was prepared using the manufacturer's recommended technique. PC was mixed with bovine thrombin and calcium chloride in the proper ratio and was sprayed into a sterile bowl containing freeze-dried cancellous allograft chips. PC used with thrombin improves the handling characteristics by consolidating the material into a unitary graft, allowing the material to be shaped as needed to facilitate placement and packing into the defect site.

In the atrophic nonunion case, the site was exposed through standard incisions and all fibrous material removed from the nonunion gap. A high-speed burr was utilized to decorticate the nonunion gap down to punctate bleeding bone so as to facilitate vascular ingrowth. Following preparation, the PC-cancellous chips composite was packed densely into the defect. Routine closures were subsequently completed.

Similar graft preparation and packing was carried out in the tibial osteomyelitis and malunion cases.

Case Reports

Case 1— Diagnosis: Tibial Osteomyelitis

A 34-year-old male presented with osteomyelitis of the distal tibial metaphysis. Magnetic Resonance Imaging demonstrated a 2.5 cm defect in the distal tibial metaphysis *(Figure 1)*. The patient's initial treatment including open debridement of the distal tibia from an anterior incision and placement of tobramycin-impregnated PMMA beads *(Figure 2)*.

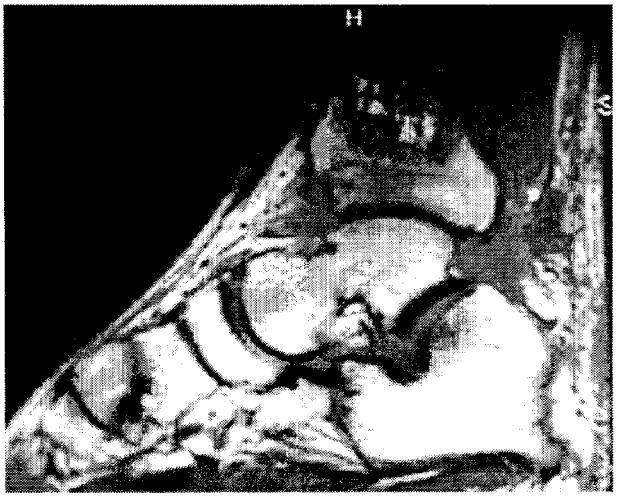

Figure 1

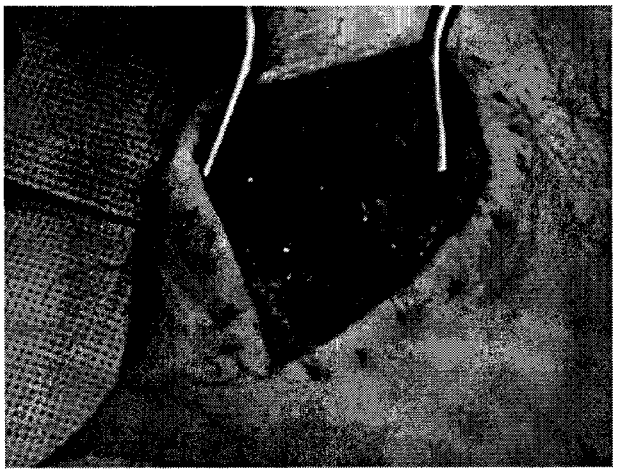

Figure 2

Three weeks postoperative, he was taken back to surgery for removal of the antibiotic beads and bone grafting of the distal tibia. The defect was filled with a composite of allograft cancellous bone chips and autologous platelet concentrate. Follow-up radiographs showed excellent healing of the bone defect *(Figures 3a and 3b)*. The patient has since resumed full weight bearing and normal daily activities.

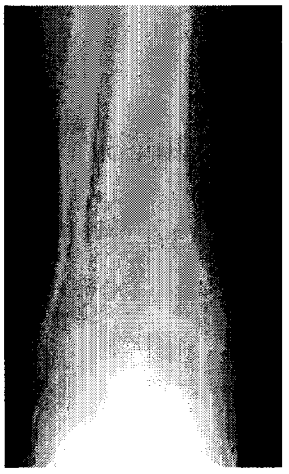

Figure 3a

Figure 3b

Case 2— Diagnosis: Tibial Shaft Nonunion

A 39-year-old female diagnosed with a tibial shaft fracture was originally treated using a cast. Ten months following surgery, she presented with a nonunion of the tibial shaft *(Figure 4)*.

Figure 4

The patient was treated with plate fixation *(Figures 5a and 5b)*. During surgery a mixture of allograft cancellous bone chips and autologous platelet concentrate were placed into the nonunion site. Follow-up radiographs taken six months after surgery showed complete healing of the nonunion site *(Figures 6a and 6b)*. The patient has returned to full function.

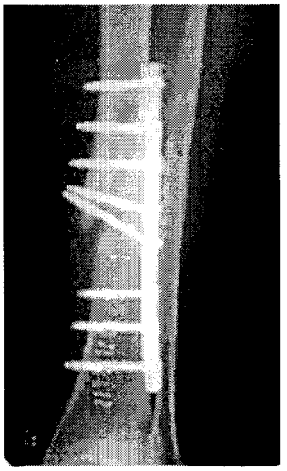

Figure 5a

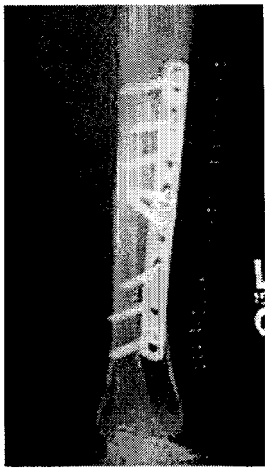

Figure 5b

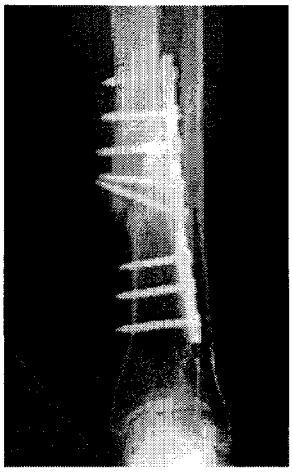

Figure 6a

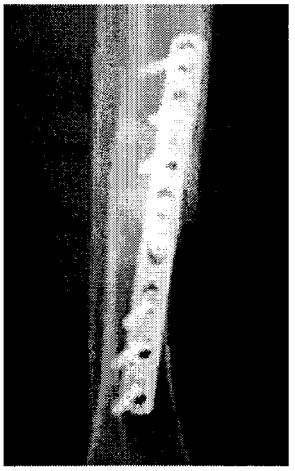

Figure 6b

Case 3— Diagnosis: Proximal Tibial Malunion

A 34-year-old female initially presented with a malunion of the proximal tibia 14 months after undergoing surgical repair of a complex bincondylar tibial plateau fracture *(Figures 7a and 7b)*. She was treated using an anterior opening wedge osteotomy of the proximal tibia with plate fixation, supplemented by a mixture of allograft tricortical, cancellous bone chips and autologous platelet concentrate *(Figures 8a and 8b)*.

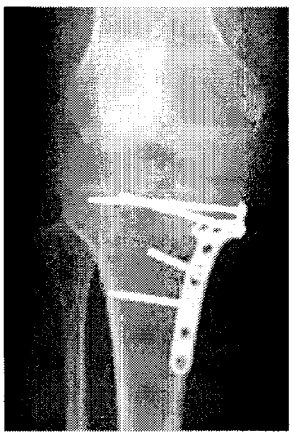

Figure 7a

Figure 7b

Figure 8a

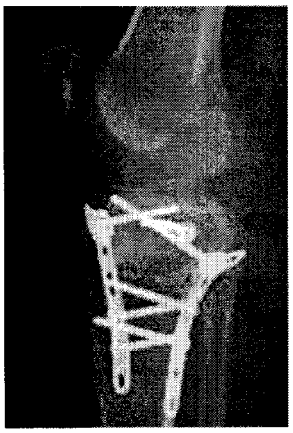

Figure 8b

Follow-up radiographs taken six months after surgery showed complete healing of the osteotomy site *(Figures 9a and 9b)*. At more than one year follow-up, there had been no collapse of the osteotomy site and the patient had returned to normal activities.

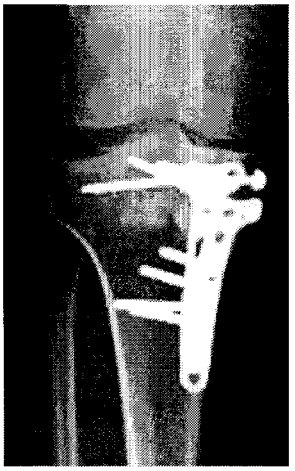

Figure 9a

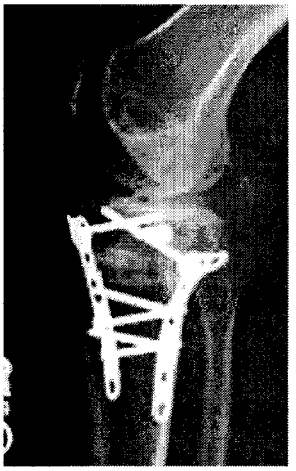

Figure 9b

Discussion

Current clinical practice indicates that skeletal fixation with autogenous bone grafting remains the gold standard for treatment of nonunion fractures in long bones. However, this method is associated with several shortcomings such as donor-site morbidity and limited availability of material that can be harvested from a single patient.[12] As an alternative, various allograft and synthetic materials are frequently used as bone graft substitutes. These materials primarily serve as a scaffold for new bone in-growth.[13]

Platelet granules contain a variety of growth factors that signal cells and impact on critically important healing and remodeling functions such as cell migration, proliferation, differentiated-function and angiogenesis.[5-6]

The clinical usefulness of PC in augmenting bone graft materials is supported by understanding the role platelets play in tissue healing and bone repair. Studies have shown that fracture healing begins immediately post-injury when growth factors are released into the fracture hematoma by circulating platelets.[14] Platelet concentrate from the Symphony PCS may enhance this initial healing response.

These studies reinforce the fact that the patient's own blood contains the growth factors necessary for the initiation and propagation of fracture healing. Symphony PCS facilitates harvesting these growth factors in a form that is clinically useful. In addition, clinical decision-making is enhanced as the platelet concentrate produced can be utilized as part of a mixture with various osteoconductive matrices.

Utilizing the patient's own blood eliminates the admittedly low, but still real, concerns about transmission of blood-borne pathogens and potential immune response. Patient safety is enhanced by the relative simplicity of the technique, automation and intra-operative preparation within the confines of the operating suite.

The small level of blood needed, usually between 55mL and 110mL, also enhances clinical options. This expands the universe of patients appropriate for the procedure by potentially adding the ability to treat smaller patients, those with anemia, prior blood donation or venous access limitations.

Potentially, Symphony PCS with bone grafting, may be used in patients where tibial malunion is a problem. As seen in this case series, PC aided recovery in nonunion of the tibial shaft and the proximal tibia. In addition, the system provided relief in a patient with osteomyelitis of the distal tibial metaphysis. In short, the Symphony system appears to be appropriate in situations where augmentation of the fracture-healing cascade is deemed to be clinically desirable.

The initial results from this procedure are promising. However, it is important to continue following these patients to better assess longer-term survival and outcomes. In addition, studies are needed to assess success rates against the autograft gold standard.

Summary

Platelet concentrate is an ideal source of autologous growth factors that help to promote bone healing. PC has the potential to minimize or eliminate the need for autogenous bone grafting which is known to be associated with significant donor site morbidity.

The Symphony PCS system is very simple, inexpensive and provides a reliable platelet concentrate that may be used in concert with a number of osteoconductive materials including calcium phosphate granules, frozen/freeze-dried cancellous bone chips or autologous bone. As the cases in this review demonstrate, PC prepared with the Symphony PCS system is readily used to help promote bone union in a number of clinical situations, including the healing of defects resulting from osteomyelitis, tibial nonunion, and reconstructive opening wedge osteotomies.

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