
Platelet Concentrate Preparation: A Comparison of the Harvest SmartPREP[®] 2 with the Biomet GPS[®] III

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INTRODUCTION

Autologous platelet concentrate (APC) is a rich source of bioactive proteins, including growth factors that modulate the healing process. By concentrating the platelets from freshly drawn peripheral blood, it is possible to create a large reservoir of growth factors to up regulate the normal healing process.

Clinically, APC is most often applied as a concentrated platelet gel following the addition of an activator (1000U Thrombin/ μ l 10% CaCl₂ solution). Upon activation, the APC releases the bioactive proteins and growth factors such as PDGF-AB, TGF- β 1, VEGF, and basic fibroblast growth factors which act locally to 1) recruit undifferentiated cells to the site of injury and 2) trigger mitosis in these cells.^{1,2}

APC has been applied clinically to facilitate both bone and soft tissue healing. The initial research conducted by Marx, et al during mandibular continuity defects of at least 5 cm showed more than a 2 fold increase in bone maturation and up to a 30% greater bone density when incorporating APC with a mean platelet concentrate of 3.4x baseline into the graft.³ Coetzee, et al and Barrow, et al both independently reported that APC significantly enhanced fusion rates and decreased frequency of nonunion during ankle surgery.^{4,5}

The effect of APC is not limited to osteoblasts. Gfatter demonstrated the efficacy of activated platelets bound on fibrin in the mitosis of fibroblasts, which (effect) is a response to growth factors secreted by platelets.⁶ Ventura, et al showed that incorporating APC into quadrupled hamstring tendon grafts resulted in significantly faster conversion to new ACL.⁷ While Trowbridge, et al showed APC use in cardiac surgery conferred a level of protection against sternal dehiscence/infection while imposing lower additional costs and did not confer additional risks.⁸

Current literature suggests a dose dependent relationship between the load of proteins delivered to the injury site and healing. It is important that the process for producing APC is capable of concentrating as many platelets from the blood sample as possible and then that these platelets can release the desired growth factors. The quality of APC must also be evaluated by two in vitro tests; platelet aggregation and P-selectin. The later test has been demonstrated to correlate with in vivo platelet survival.

OBJECTIVE

The study was designed to compare the platelet concentrate (PC) prepared by the SmartPREP[®] 2 (Harvest Technologies, Plymouth, MA) with the GPS[®] III (Biomet Manufacturing Corp, Warsaw, IN). The SmartPREP 2 utilizes an automated dual spin centrifugation process while the GPS III uses a single spin centrifugation process to separate the platelets from whole blood.

MATERIALS AND METHODS

140 mL of ACD-A/Whole blood was collected by syringe from 5 normal donors. The blood sample from each donor was placed into a transfer bag prior to processing. Thus, all baseline samples and required blood volume for processing by each of the manufacturer's devices were identical. 60 mL of the anticoagulated whole blood from each donor was processed in each system according to the manufacturer's instructions for each donor.

RESULTS

Table 1 compares the processing details of each of the systems. The SmartPREP 2 requires significantly less sterile barrier entries and processing steps than the GPS III. The SmartPREP 2 has an automated 14 minute centrifugation time at a maximum g-force of 1,000g's. The GPS III centrifuge is manually set to 3,200 RPM (approximately 1,900 g's) and process time to 15 minutes. Since this system is not processed using a brake the coast down time adds an additional 4 minutes at relatively high g force. The total time needed to prepare platelet concentrate was 42% faster with the SmartPREP 2 system.

Table 1: Comparison of the Processing Details Excluding Phlebotomy
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| System | Anticoagulated Blood Volume Processed (ml) | Number of Sterile Barrier Entries | Number of Processing Steps | Operator Time (min) | Process Time (min) | Total Time (min) |
|---------------------|--|-----------------------------------|----------------------------|---------------------|--------------------|------------------|
| Harvest SmartPREP-2 | 60 | 4 | 6 | 5 | 14 | 19 |
| Biomet GPS III | 60 | 7 | 16 | 8 | 19 | 27 |

Table 2 summarizes and compares the platelet products produced by both systems. The SmartPREP 2 produced platelet rich plasma with an average volume of 10.2 mL compared to 7.6 mL with the GPS III system. As compared to the GPS III, the SmartPREP 2 recovered a significantly greater percentage of platelets (71.8% v. 51.4, p=0.03), delivered a significantly greater total number of platelets ($10,163 \times 10^6$ v. $7,194 \times 10^6$, p=0.001), with a significantly lower co-efficient of variation (4.2% v. 20.4%).

| Table 2 - Comparison of Platelet Products (n=5) CBR Institute Biomedical Research, Boston, MA | | | | | | |
|---|---|------------------------------|--|------------------|---|----------------------------|
| System | Baseline Platelet Count x 10 ³ /ml | Platelet Concentrate Vol. mL | Platelet Concentrate x 10 ⁶ /mL | Platelet Yield % | Total Platelets Delivered x 10 ⁶ /mL | Coefficient of Variance, % |
| Harvest SmartPREP-2 | 238 ± 33 | 10.2 ± 0.27 | 994 ± 132 | 71.8 ± 3.04 | 10,163 ± 1,595 | 4.2 |
| Biomet GPS III | 238 ± 33 | 7.6 ± 0.74 | 943 ± 125 | 51.4 ± 10.5 | 7,194 ± 1,515 | 20.4 |

Haynesworth showed in vitro and Sclafani demonstrated in an animal model the dose dependent relationship between growth factor load and cell proliferation (an indicator of healing).^{9, 10}

The SmartPREP 2 system incorporates the flexibility to “dose” the final platelet concentration whereas the GPS III system has a fixed end product volume of approximately 7 mL. Table 3 standardizes the platelet rich plasma data for 7 mL and 10 mL end product volumes. The SmartPREP 2 had a 39% greater increase above baseline than the GPS III system.

| Table 3: Standardized Comparison of Platelet Products | | | |
|--|---|-------------------------------|----------------------------|
| System | Increase Above Baseline for 60 mL of Process Volume | | Coefficient of Variance, % |
| | 7 mL of Platelet Concentrate | 10 mL of Platelet Concentrate | |
| Harvest SmartPREP 2 | 6.1x | 4.3x | 4.2% |
| Biomet GPS III | 4.4x | 3.1x | 20.4% |

CONCLUSION AND SUMMARY

Recovering high concentrations of viable platelets and their resulting growth factors represent the most important factors in the clinical utility of platelet concentrate. P-selectin expression showed neither the SmartPREP 2 nor GPS III systems pre-activate platelets in the preparation of PRP. Comparative testing versus the GPS III showed that the SmartPREP 2 system consistently produced platelet concentrate with higher platelet yields, increase above baseline, and total number of cells delivered. The SmartPREP 2 system also recovered the platelets in the shortest amount of time and with the greatest level of reproducibility.

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