Bone Marrow Concentrate Isolation Using the PXP® System

Enhancing bone marrow concentrate isolation and removing unwanted red blood cells using a quick automated process.

INTRODUCTION

Bone marrow concentrate (BMC) is a biological sample derived from a patient’s own bone marrow that is highly rich in mesenchymal stem cells (MSCs) and hematopoietic stem cells (HSCs). These cells are critical for tissue regeneration and bone formation. Despite the advancements of automated systems for processing of bone marrow over the years, the quality of the concentrates are still difficult to assess and contain a great deal of red blood cell (RBC) contamination despite being optimized for high cell recoveries.\(^2\)\(^4\)

The composition of the final cell product and the potential effect of contaminating RBCs are questionable. Studies have shown that the number of contaminating RBCs in the purified BMC population might influence the viability and functionality of the cells used in therapies.\(^1\)

Reduced hematocrit in the BMC would result in better functionality of the progenitor cells used in the cell therapy, which is not the focus of BMC devices currently available on the market.
**PXP® SYSTEM**

**BMC PROTOCOL USING THE PXP® SYSTEM**

The PXP System is a closed automated system that harvests a precise volume of cell concentrate from a bone marrow aspirate sample with extremely low RBC contamination. Its ability to achieve consistently high MNC and CD34+ recoveries in less than 20 minutes, along with negligible RBC contamination, sets this system apart from its competitors.

**PROCESS FLOW**

1. **TRANSFER BONE MARROW ASPIRATE INTO THE DISPOSABLE CARTRIDGE.**
2. **LATCH DISPOSABLE CARTRIDGE ONTO CONTROL MODULE AND CENTRIFUGE.**
3. **WITHDRAW HARVEST FRACTION BY SYRINGE.**
4. **PLACE THE CONTROL MODULE ON THE DOCKING STATION AND DOWNLOAD PROCESSING DATA.**

**METHODS**

To evaluate the efficiency of bone marrow processing using the PXP System, five anti-coagulated bone marrow samples were drawn from individual donors and processed using the ThermoGenesis PXP System. All samples were drawn less than 8 hours prior to processing and a 60 mL input volume was loaded into each PXP Disposable Cartridge. The cartridges were then latched onto a PXP Control Module programmed for BMC isolation, loaded into a centrifuge containing round swinging buckets, and processed using the following centrifugation protocol:

- 2000 x g for 8.5 minutes to sediment sample into different fractions
- 50g x g for 2 minutes for bulk depletion of RBCs
- 500g x g for 2 minutes for further sedimentation of residual RBCs
- 50 x g for 1 minute for a final depletion of RBCs
- 250 x g for 30 seconds to sediment targeted cells prior to the harvest cycle
- 50 x g for 1 minute to harvest cell concentrate into the harvest chamber of the Disposable Cartridge
RESULTS

The PXP System produced high MNC recoveries of 99.6%, while depleting greater than 99.1% of RBCs. Average MNC fold changes and CD34+ concentration factors were 9.7-fold and 12.98-fold respectively and the harvest volume was 6.2 mL with a low standard deviation (0.7 mL).

CONCLUSION

The BMC protocol using the ThermoGenesis PXP System greatly reduced the amount of RBC contamination in the final product and was able to deplete greater than 99% of RBCs in the final product (based on Graph 1) while averaging 9.7-fold change for MNC and an increase of CD34+ concentration factor of 12.98-fold compared to the initial sample.

The PXP System addresses many shortcomings of currently available systems on the market, most notably, red blood cell contamination in the final cell concentrate which is believed to diminish efficacy of cell treatments. The system will allow clinicians to quickly and efficiently achieve high MNC and CD34+ recoveries along with a precise harvest volume.
ADVANTAGES

- Consistently high MNC and CD34+ recoveries
- Greater than 99% RBC depletion (as shown in Graph 1)
- Rapid concentration of bone marrow in less than 20 minutes
- Automated, closed and sterile system
- Quick and accurate data tracking and documentation

REFERENCES