Background

The MarrowXpress Platform (MXP) is intended for the preparation of stem cell concentrates from bone marrow aspirate at the point of care or in a laboratory setting. The system consists of a microprocessor-controlled, software-operated device with an optical sensor. The device is utilized with a dedicated disposable set consisting of multiple, sterile bags and a microprocessor-controlled valve to direct fluid movement. The fluid path within the disposable is sterile, non-gyrogenic and functionally closed. The system delivers an operator-selected volume of stem cell concentrate into the product bag in 45 minutes of total processing time.

The goal of this study was to evaluate the MXP concentration process of human bone marrow under intended use conditions.

Methods

Informed consent was obtained from all patients who participated in this study. Bone marrow aspirate was collected in an operating room from patients using heparin and ACD-A as anticoagulants. Bone marrow aspirate (50 mL to 120 mL) was concentrated into a cell concentrate by the MXP process to a final volume of 10 to 20 mL according to the target volume selected by the MXP operator. Complete blood counts were measured using Sysmex XE-2100 cell counter for pre-MXP processed and post-MXP processed (cell product) samples. CD34+ cells and cell viability were measured by flow cytometry using StemKit (Beckman Coulter, Brea, CA). The cell recovery was calculated by dividing the total cell numbers in the final product by the total cell numbers in pre-MXP processed bone marrow aspirate.

Fig 1. Blood and hematopoietic stem cell recovery post-MXP process. Human bone marrow sample of pre-MXP and post-MXP process were aseptically taken and measured for MNC, WBC and platelet using Sysmex 2100 cell counter. The samples were also measured for CD34 cells with flow cytometry. The value of the cell count was used to calculate the cell recovery dividing the total cell count in the post-MXP sample by the total cell count in the pre-MXP sample. The value is expressed as the mean±SD.

Fig 2. RBC recovery (%) and RBC mass (ml) in MXP-processed BM product. The value is expressed as the mean±SD.

Fig 3. The MarrowXpress process did not affect cell viability. There was no significant difference of cell viability between pre-MXP and post-MXP samples (p value = 0.158). Cell viability was determined by flow cytometry with StemKit using 7-ADD.

Table 1. Cell counts in pre-MXP and post-MXP samples and their enrichment after the MXP process. The value is expressed as the mean±SD.

<table>
<thead>
<tr>
<th></th>
<th>WBC</th>
<th>MNC</th>
<th>Platelet</th>
<th>CD34+ Cell*</th>
</tr>
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<tbody>
<tr>
<td>Pre-MXP</td>
<td>21±10</td>
<td>4.9±2.2</td>
<td>100±35</td>
<td>15±13</td>
</tr>
<tr>
<td>Post-MXP</td>
<td>89±43</td>
<td>27±13</td>
<td>426±222</td>
<td>89.3±75</td>
</tr>
<tr>
<td>Enrichment Factor</td>
<td>×4.2</td>
<td>×5.5</td>
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* CD34+ cell counts is presented as 10^4/mL.

Results

The MarrowXpress Platform (MXP) is intended for the preparation of stem cell concentrates from bone marrow aspirate at the point of care or in a laboratory setting. The system consists of a microprocessor-controlled, software-operated device with an optical sensor. The device is utilized with a dedicated disposable set consisting of multiple, sterile bags and a microprocessor-controlled valve to direct fluid movement. The fluid path within the disposable is sterile, non-gyrogenic and functionally closed. The system delivers an operator-selected volume of stem cell concentrate into the product bag in 45 minutes of total processing time.

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Conclusions

- The MXP system is a reliable and reproducible method to reduce human bone marrow volume for the preparation of stem cell concentrates.
- The MXP system is suitable for clinical use at the point of care.
- The stem cells and platelets are concentrated on average 5.9x and 4.3x, respectively above baseline by MXP processing.
- Excellent hematopoietic stem cell recovery is coupled with reproducible volume reduction and RBC reduction.