SAFE BLOOD RECOVERY + SAFE BLOOD REINFUSION = DONOR™ SYSTEM
SAFE BLOOD RECOVERY
+ SAFE BLOOD REINFUSION
= THE DONOR™ SYSTEM

Blood conservation

Concerns over safety, availability and increasing costs of allogeneic blood products have led to a review of autologous programs within many hospitals. One relatively under-utilised source of autologous blood is the post-operative collection of wound drained blood. Use of wound drained blood has been shown to significantly reduce allogeneic transfusion requirements and their associated costs.

To be effective, wound drained blood must be collected and re-infused safely.

Blood reinfusion

There is some concern over the quality and safety of reinfused unprocessed wound drained blood which may contain the following contaminants:

- fat
- microaggregates
- surgical & tissue debris
- activated leukocytes
- activated platelets
- activated complement proteins
- cytokines & bioactive substances
- activated thrombin, procoagulants
- fibrin degradation products

The use of unprocessed, unfiltered wound drained blood may result in complications such as fat embolism syndrome (neuro and pulmonary dysfunction), microcirculatory obstructions, non-haemolytic febrile transfusion reactions, complement activation and coagulation disorders.

Intermittent suction: generally provided by spring loaded "bellow" type devices. These devices have been associated with reduced draining capability, wound healing and increased wound infection when compared to continuous suction devices.

Continuous suction: demonstrated improved wound healing, reduce the incidence of haematoma, infection and drain blockage.

Berman et al. reported in a randomised prospective trial involving 126 orthopaedic surgical wounds, that "A clear advantage to using a continuous vacuum suction device over an intermittent spring loaded device is seen with respect to hematoma evacuation, wound drainage, wound healing, and possible complications."

This type of continuous suction can be provided from wall-mounted vacuums which may limit patient manœuvreability, or electrical/battery powered pumps which may be bulky and difficult to use.

SEM photograph of debris from salvaged blood on filter media

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Due to these concerns, some clinicians elect to use cell-washing techniques in order to reduce soluble contaminants from salvaged wound drained blood. However, cell-washing procedures may still leave significant levels of fat\(^{14}\), activated leukocytes\(^{15,17,18}\) and debris in the recovered product.

### Comparison of leucocyte reduction (%) capability of 6 cell wash autotransfusion machines

<table>
<thead>
<tr>
<th>Machine</th>
<th>Compact A</th>
<th>C.A.T.S.</th>
<th>Sequestra</th>
<th>AutoLog</th>
<th>Cell Saver</th>
<th>Brait II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leucocyte</td>
<td>81 ± 7</td>
<td>26 ± 14</td>
<td>76 ± 8</td>
<td>91 ± 1</td>
<td>82 ± 11</td>
<td>39 ± 10</td>
</tr>
<tr>
<td>Reduction %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Residual leukocytes within these processed blood products are known to be highly activated\(^{14}\) and can result in patient tissue damage on reinfusion\(^{19}\). Considerable concern has also been given to the fat removal capacity of cell-washing machines, where it has been documented that non-continuous cell washers offer little protection from the hazards of fat.

Brocke and co-workers\(^{14}\) concluded that, "Blow-based autotransfusion devices reduce the amount of fat found in shed blood, but cannot completely eliminate fat particles. When fat is seen on the surface of the processed blood, this blood should be filtered with a leucocyte depletion filter before retransfusion."

**DONOR\(^{TM}\) pre-evacuated post operative autologous blood reinfusion system**

DONOR\(^{TM}\) is a patented system involving the integration of two market leading technologies for the post-operative collection and reinfusion of wound drained blood. The system includes:

- 800 mL, chlorine free pre-evacuated collection vessel
- Vacuum regulator
- Connection tube with slide clamp and anti-reflux valve and connector
- Air vent with 0.2 mm hydrophobic membrane filter and breakaway cap
- Integrated injection port
- Scalpel tipped trocar with pre-attached wound drains
- Integrated Pall LipiGuard\(^{TM}\) VS Reinfusion Filter for Salvaged Blood, with attached blood administration set
- 600 mL pre-evacuated replacement drainage vessel

Clinical and laboratory evaluation of the DONOR\(^{TM}\) constant vacuum aspiration technology demonstrates no significant haemolysis.

### Performance characteristics of the DONOR\(^{TM}\) Collection Vessel for Plasma Haemoglobin

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Pre-aspiration</th>
<th>Post-aspiration</th>
<th>Post-aspiration + 6 hour hold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean of 10 Samples</td>
<td>&lt;0.05 mMol/dL (0.04%)</td>
<td>&lt;0.04 mMol/dL (0.03%)</td>
<td>&lt;0.04 mMol/dL (0.03%)</td>
</tr>
<tr>
<td>(Haemolysis %)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**LipiGuard\(^{TM}\) VS - safe blood reinfusion**

The DONOR\(^{TM}\) System also includes the Pall LipiGuard\(^{TM}\) VS Reinfusion Filter for Salvaged Blood with attached blood administration set incorporating a self-leveling drip chamber for enhanced ease of use. This filtration system significantly reduces the concentration of:

- Fat
- Microaggregates
- Activated complement protein C3a
- Leucocytes

In the salvaged blood, thus prophylactically protecting the patient against fat embolism syndrome, microcirculatory blockage, tissue damage and activated complement anaphylaxis upon reinfusion.

**Performance characteristics of the Pall LipiGuard\(^{TM}\) VS Reinfusion Filter for Salvaged Blood**

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SAFE BLOOD RECOVERY + SAFE BLOOD REINFUSION = THE DONORM SYSTEM

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Summary

The unique DONORM™ Pre-Evacuated Post-Operative Autologous Blood Reinfusion System provides a safe and user-friendly option for utilising a patient’s wound drained blood, leading to a reduction in the usage of allogeic blood products, their associated risks and costs.

References


DONORM® is a concept of Van Straten Medical with the use of exclusive Pall technology.

Manufactured by Medinorm AG, Germany
INTRODUCTION
Since the Better Blood Transfusion Directive (Department of Health HSC 2002/009 2002), hospitals have been assessing post-operative cell salvaged blood to reduce costs and exposure to allogeneic blood in selected patient groups. However salvaged blood may contain significant levels of contaminants such as lipid, activated leucocytes and particulates that, on reinfusion to the patient, can lead to adverse clinical events such as febrile reactions, pulmonary dysfunction and fat embolism syndrome.

The aim of this study was to assess the practical aspects of using the system with unwashed salvaged wound drain blood collected into the DONOR™ system, and to gain performance data for leucocyte and fat removal.

The DONOR™ system (Pall Medical) provides a complete collection and reinfusion system. It consists of a pre-evacuated primary cannister with several “automatic” features and incorporates a Pall LipiGuard VS filter re-infusion filter set designed for the reduction of fat particles, anaphylatoxin C3a, leucocytes and microaggregates from up to 800 mL of post-operatively salvaged blood.

METHODS:
Blood was collected into the DONOR pre-evacuated collection canister from wound drains following total knee replacement (n=11 patients). Typically bleeding stopped within 2 hours. A secondary pre-evacuated cannister was attached in a closed and safe manner to maintain negative pressure on the wound site. The blood collected in the primary cannister was analysed in a laboratory.

Measurements of the salvaged blood were performed pre- and post-filtration for:
- Leucocytes
- Fat
- Plasma haemoglobin

Leucocyte counting was performed using the ADVIA 120 haematology analyser. This analyzer is accurate for leucocyte counting down to 0.02 x 10^9/L.

Fat droplet counting was performed using a Laborlux K microscope with Fluorescence light source (Leitz, UK) and H2 excitation filter (390-490 nm). Fat droplets were stained with Nile Red Stain (Nile Blue A-Oxazone-Sigma). Fat droplets were counted on a Neubauer counting chamber, the size of the droplets was measured with an eyepiece graticule and the concentration measured by comparison with “Flow Count” fluorospheres (Beckman Coulter, UK).

RESULTS:

<table>
<thead>
<tr>
<th>Laboratory Data (n=11)</th>
<th>Pre-Filtration</th>
<th>Post-Filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Volume (mL)</strong></td>
<td>314 +/- 168</td>
<td>277 +/- 169</td>
</tr>
<tr>
<td><strong>Haemoglobin (g/dL)</strong></td>
<td>10.2 +/- 2.5</td>
<td>9.6 +/- 2.8</td>
</tr>
<tr>
<td><strong>Leucocytes (x10E9/L)</strong></td>
<td>4.4 +/- 1.8</td>
<td>1.0 +/- 0.5</td>
</tr>
<tr>
<td><strong>Plasma Haemoglobin (mg/dL)</strong></td>
<td>87.8 +/- 22.7</td>
<td>85.3 +/- 21.2</td>
</tr>
<tr>
<td><strong>Lipid Particles</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;100 µm/µL</td>
<td>2 +/- 5</td>
<td>0</td>
</tr>
<tr>
<td>51-100 µm/µL</td>
<td>17 +/- 16</td>
<td>0</td>
</tr>
<tr>
<td>21-50 µm/µL</td>
<td>100 +/- 50</td>
<td>10 +/- 9</td>
</tr>
<tr>
<td>10-20 µm/µL</td>
<td>492 +/- 276</td>
<td>84 +/- 63</td>
</tr>
</tbody>
</table>

- Reduction of fat particles was highly significant (p< 0.0001, Chi square test)
- Average leucocyte reduction was 77%
- Average fat particle reduction was 86%
- The small volume fluid loss was due to clots and visible fat retained in the system
- One patient had blood re-infused from three primary DONOR™ re-infusion systems within the 6 hour period, a total of 1630mL blood.

CONCLUSION:
The DONOR™ system was found to be very easy to use by both theatre and ward personnel, particularly connection to patient, one button activation of the drain, easy to measure volume of blood and automatic filter and drip chamber priming.

The Pall LipiGuard VS filter is effective at reducing lipid particles and leucocytes from the salvaged blood, offering prophylactic protection against clinical sequelae of reinfusion, such as fat embolism syndrome, febrile reactions and pulmonary dysfunction. The system did not induce haemolysis.

The reduction in patient haemoglobin indicates that patients with 13 Hb g/dL pre-operatively would most benefit from use of the DONOR device to prevent a drop below an 8 Hb g/dL transfusion trigger.

The authors wish to thank the orthopaedic surgeons for their assistance. Further studies are ongoing.
P43. Evaluation to Assess the DONOR™ Pre-Evacuated Post-Operative Autologous Blood Re-Infusion System

J. M. Davies & D. L. A. Aston. The North Hampshire Hospital, Basingstoke, Hants

The transfusion of homologous blood has many risks, and this, coupled with the probability that donated blood may soon be a scarce resource, has led to a widespread interest in blood conservation. The transfusion of autologous, salvaged blood is a method by which homologous blood could be avoided in the surgical setting. In orthopaedic and cardiac surgery, there may be considerable quantities of fat and activated leucocytes in the salvaged blood, which must be removed prior to re-infusion. The aim of this evaluation was to assess the practical aspects of using the system with unwashed, salvaged wound drain blood collected into the DONOR™ system, and to gain performance data for leucocyte and fat removal.

Measurements of the salvaged blood were performed pre- and post-filtration; these included leucocyte counts, fat particle counts, container weights, full blood count, urea and electrolytes, plasma haemoglobin and complement testing. The results showed that there was a 70% reduction in leucocyte count post-filtration and an 80% reduction in fat droplets. Haemoglobin, platelet and urea and electrolyte counts remained unchanged by filtration.

The DONOR™ system is very simple to use and our results show that it is effective in removing leucocytes and fat particles. This system is probably most effectively used in those patients expected to bleed excessively, those with low haemoglobins preoperatively and those undergoing operations in a remote hospital with no on-site transfusion department.

Presented at BBTS, Edinburgh. 2002
Reprinted with permission from Transfusion Medicine, Vol 12 (Suppl 1), pp 38-39. 2002
Evaluation to assess the practical handling, leukoreduction and fat removal characteristics of the DONOR™ pre-evacuated post-operative autologous blood re-infusion

INTRODUCTION
- Donated blood may soon be a scarce resource and has potential risks
- The transfusion of autologous, salvaged blood is a method by which donated blood could be avoided in the surgical setting
- Blood recovered by postoperative blood salvage requires filtration prior to re-infusion and cannot be transfused to other patients
- Salvaged blood may contain activated leucocytes which may cause lung damage and fat particles which may cause fat embolic syndrome
- The DONOR™ (Pall Medical) system is CE marked and validated for the re-infusion of post-operatively salvaged blood
- The DONOR™ system includes a LipiGuard VS (Pall Medical) re-infusion filter set designed for the reduction of fat particles, anaphylatoxin C3a, microaggregates and leucocytes from up to 800 mL of post-operatively salvaged blood
- The aim of this evaluation was to assess the practical aspects of using the system with unwashed salvaged wound drain blood collected into the DONOR™ system, and to gain performance data for leucocyte and fat removal

MATERIALS AND METHODS
- Blood was collected from wound drains post total knee replacement
- Measurements of the salvaged blood were performed pre- and post-filtration for:
  - Leucocytes
  - Fat
  - Plasma haemoglobin
- Leucocyte counting was performed using the ADVIA 120 haematology analyser. This analyser is accurate for leucocyte counting down to 0.02 x 10^9/L
- Fat droplet counting was performed using a Laborlux K microscope with Fluorescence light source (Leitz, UK) and H2 excitation filter (390-490 nm). Fat droplets were stained with Nile Red Stain (Nile Blue A-Oxazine- Sigma). Fat droplets were counted on a Neubauer graticule and the concentration measured by comparison with “Flow Count” fluorospheres (Beckman Coulter, UK)

RESULTS
Phase 1
- The following table shows the measurements of the wound drainage fluid pre- and post-filtration (mean ± SD, n=11)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-filtration</th>
<th>Post-filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin (g/L)</td>
<td>102 ± 25</td>
<td>96 ± 28</td>
</tr>
<tr>
<td>Leucocytes (x 10^9/L)</td>
<td>4.4 ± 1.8</td>
<td>1.0 ± 0.5</td>
</tr>
<tr>
<td>Platelets (x 10^3/µL)</td>
<td>30 ± 16</td>
<td>14 ± 5</td>
</tr>
<tr>
<td>Plasma Haemoglobin (mg/dL)</td>
<td>87.8 ± 22.7</td>
<td>85.3 ± 21.2</td>
</tr>
<tr>
<td>Fat (µm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-10</td>
<td>2 ± 3</td>
<td>0</td>
</tr>
<tr>
<td>11-50</td>
<td>17 ± 16</td>
<td>0</td>
</tr>
<tr>
<td>51-100</td>
<td>100 ± 50</td>
<td>10 ± 9</td>
</tr>
<tr>
<td>Fat (10-20 µm)</td>
<td>492 ± 276</td>
<td>84 ± 63</td>
</tr>
</tbody>
</table>

- Fat droplets observed using fluorescent microscopy (Mag x100)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-filtration</th>
<th>Post-filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative Hb</td>
<td>g/L</td>
<td>141 ± 9</td>
</tr>
<tr>
<td>Post-operative Hb</td>
<td>g/L</td>
<td>105 ± 14</td>
</tr>
<tr>
<td>Volume of blood collected in wound drain mL</td>
<td>314 ± 168</td>
<td>834 ± 337</td>
</tr>
<tr>
<td>Total blood loss mL</td>
<td></td>
<td>1080 ± 390</td>
</tr>
<tr>
<td>Length of hospital stay days</td>
<td></td>
<td>8 ± 2</td>
</tr>
</tbody>
</table>

- Expected minimum length of stay for total knee replacement is 5 days
- One patient had cerebrovascular accident (CVA) and died 17 days post-operatively

Phase 2
- The following table shows the results from patients enrolled in Phase 2 of the evaluation, (mean ± SD n=10)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-filtration</th>
<th>Post-filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative Hb</td>
<td>g/L</td>
<td>143 ± 17</td>
</tr>
<tr>
<td>Post-operative Hb</td>
<td>g/L</td>
<td>106 ± 15</td>
</tr>
<tr>
<td>Volume of blood collected in wound drain mL</td>
<td>579 ± 83</td>
<td></td>
</tr>
<tr>
<td>Total blood loss mL</td>
<td></td>
<td>1080 ± 390</td>
</tr>
<tr>
<td>Length of hospital stay days</td>
<td></td>
<td>8 ± 2</td>
</tr>
</tbody>
</table>

- One patient required allogeneic blood for gastro-intestinal haemorrhage
- One patient with myeloma required allogeneic blood post-operatively for anaemia
- One patient had blood re-infused from three primary DONOR™ re-infusion systems within the 6 hour period, a total of 1630 mL blood
- No patients suffered infection
- No patients were re-admitted

CONCLUSION
- The DONOR™ system is safe and easy to use:
  - easy to connect to patient
  - one button activation of drains
  - preferable to bellows system
  - easy to measure volume of blood
  - hands free filter + drip set priming
- Pall LipiGuard VS filter is effective at reducing leucocytes and fat particles
- Filtration does not induce haemolysis
- Most effectively used in patients likely to require blood transfusion e.g. patients with low haemoglobin levels pre-operatively, patients with bleeding disorders
- The average volume of blood collected in the primary re-infusion system for the 21 patients enrolled in the trial was 430 mL, the volumes ranged from 60 mL to 700 mL
- In one freely bleeding case more than one primary DONOR™ re-infusion system was used to re-infuse 1630 mL

Davies, J.M. and Aston, D.L. The North Hampshire Hospital, Alderston Road, Basingstoke, Hants. RG24 9NA.

North Hampshire Hospitals
NHS Trust
An evaluation of Post-Operative Autologous Blood Reinfusion System in total knee replacement: The DONOR™ system


INTRODUCTION
The benefits of autologous transfusion compared with allogeneic blood are numerous. They include a reduction in transfusion reactions, a reduction in exposure to blood-borne infectious agents, reduced transfusion auto-immunity reactions as well as significant cost savings.

The aim of this study was to evaluate the introduction of a pre-evacuated post-operative autologous blood reinfusion system for patients undergoing total knee replacement surgery concentrating specifically at pre-operative and post-operative haemoglobins, and discharge.

The DONOR™ system (Pall Medical Ltd) was used. This provides a complete, easy to use collection and reinfusion system.

METHOD
DONOR™ post-operative autologous blood reinfusion systems were used instead of simple vacuum drains in a series of consecutive patients (n=10) undergoing total knee replacement surgery. Pre and post-operative haemoglobin values and days to discharge were recorded. These patients were then matched with patients undergoing the same surgery two weeks prior to this evaluation.

RESULTS
In the reinfusion system group (Group A) none of the patients required an allogeneic transfusion. In the vacuum drain group (Group B) one patient required a transfusion. In group A the mean decrease in haemoglobin after surgery was 2.6 g/dL. In Group B it was 3.8 g/dL. A Mann-Whitney U test showed a statistically significant difference between groups A and B (p=0.0026). The average length of hospital stay in Group A was 7.6 days compared with 10.4 days in Group B (p=0.16).

CONCLUSIONS
Although this is a small study the use of the post-operative autologous blood reinfusion system significantly increased the post-operative haemoglobin in total knee replacement patients. Length of hospital stay in the reinfusion group was less than the vacuum drain group but this was not shown to be statistically significant. A larger randomised controlled trial will be needed to verify these results.

Acknowledgement
The authors would like to thank Dr Roy Powell, Research & Development, Royal Devon & Exeter Hospital for his assistance with the statistics.

References
2. Berger A. Why is it important to reduce the need for blood transfusion and how can it be done? BMJ 2002;324:1302-3
**In-Vitro Testing of the DONOR™ Pre-Evacuated Post-Operative Autologous Blood Reinfusion System**

Authors: Dr. P.F. van der Meer, Blood Bank North Holland, Amsterdam
Elise Maynard Scientific and Laboratory Services, Pall Europe Ltd, Portsmouth

**Purpose**

To confirm the in-vitro performance characteristics of the DONOR™ Autologous Blood Reinfusion System.

**Summary**

- **Flow-rate**
  - this was controlled during testing to give a range of both clinical flows i.e. 2 - 12 mL/min and free flow i.e. approx. 20-60 mL/min

- **DONOR™ System Recovery**
  - mean approx. 80%. This weight loss also included the removal of macroscopic clots

- **Leucocyte Reduction**
  - mean > 81%

- **Lipid Droplet Removal**
  - mean 96% - 100 % for lipid droplets >10 µm in size

- **Plasma Haemoglobin**
  - < 0.1 mM/L

Photomicrographs of VS1 media showing particulate material, WBC and lipid
Introduction

The DONOR™ reinfusion system is a continuous pre-evacuated, closed wound drainage system that is indicated for drainage of up to 800 mL of blood from wounds and body cavities and subsequent filtration and reinfusion using the PALL LipiGuard™ VS Filter Set.

The aim of this in-vitro evaluation was to gain performance data for a variety of haematological parameters including leucocyte reduction, lipid reduction and plasma haemoglobin concentration with unwashed wound drain blood salvaged from orthopaedic operations and collected into the DONOR™ system.

Materials and methods

- Salvaged blood was collected into DONOR™ systems according to instructions for use (IFU) and labelled appropriately.
- The DONOR™ system was transported to the laboratory and the contents mixed well prior to sampling.
- The system was weighed after sampling and the tare weight noted.
- The filter set was removed from the base of the DONOR™ system and a sampling bag attached to the end of the administration set.
- The filter set and administration set were primed according to the IFU.
- Blood was filtered either under gravity (i.e. 1M head height from the top of the initial fluid level) with no flow-control or at approximately 2-12 mL/min, using the administration set roller clamp to control flow.
- Filtered blood was weighed and sampled.
- Both pre and post filtration blood samples were sampled for full blood count (FBC) using an automated cell analyser.
- Lipid droplet count was performed by fluorescence microscopy.
- Plasma haemoglobin (Hb) was determined by measurement of optical density at 560nm, 576nm and 592nm, which allows for correction for non-specific absorption of bilirubin and other pigments.
- C3a was determined using Enzyme Immunoassay.
- Filters were observed using Scanning Electron Microscopy (SEM) and Electron Dispersive X-ray Microanalysis Spectroscopy (EDS).

Results

A total of 21 systems were tested.

Flow-rate was controlled during testing to give a range of clinical flows i.e. 2 -12 mL/min. Maximum free flow under 1M head height gravity was between approx. 20-60 mL/min.

The RBC data summary is shown in Table 1. There were no clinically significant changes in platelet (PLT) and red blood cell (RBC) count pre and post filtration. The white blood cell (WBC) count was reduced by at least 81% in this study (see Graph 1). A number of the counts were at or below the sensitivity of the analyser and thus the efficiency of the filter is likely to be better than that quoted.

The mean haematocrit (HCT) was 23%, mean total Hb was approximately 5 mM/L and mean free plasma Hb was <0.1 mM/L (see table 2).

Lipid droplet reduction improved with increasing droplet size. Droplets >10µm in size were preferentially removed with mean filter efficiencies of between 96% - 100% (see graph 2).

C3a was reduced after filtration by approximately 40% (see graph 3).

SEM pictures are shown in the photomicrographs. EDS examination identified all the material to be of organic origin.

Discussion

- The DONOR™ reinfusion system was found to be very easy to use both in the theatre environment and during the reinfusion phase.
- The PALM LipiGuard™ VS filter set primed very easily due to the incorporation of a self-levelling drip chamber. This technology allows the system to prime under gravity.
- The parameters under test did not differ significantly with flow-rate. Thus the system can be used to reinfuse blood at a wide range of flow-rates. The recovery of blood from the whole system was in excess of 80%.
- RBC concentrations and haemolysis remained clinically unchanged after the entire collection and reinfusion process, thus demonstrating that the cells were not damaged.

In general, autologous transfusions are regarded as safe especially with regard to immunosupression (increased risk of infection), allosensitisation (increased risk of rejection) and reduction in patient anxiety (as they have their own blood reinfused). The unique DONOR™ Pre-Evacuated Post-Operative Autologous Blood Reinfusion System provides an option for reinfusing patients with enhanced safety and ease of use.

### Table 1: Full blood count data summary

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-Filtration</th>
<th>Post-Filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLT x 10E+09/L</td>
<td>56</td>
<td>56</td>
</tr>
<tr>
<td>RBC x 10E+12/L</td>
<td>1.15</td>
<td>1.0</td>
</tr>
<tr>
<td>WBC x 10E+09/L</td>
<td>0.9</td>
<td>0.9</td>
</tr>
</tbody>
</table>

### Table 2: Haemoglobin content

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-Filtration</th>
<th>Post-Filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hb (mM/L)</td>
<td>4.7</td>
<td>4.7</td>
</tr>
<tr>
<td>Plasma Hb (mM/L)</td>
<td>0.08</td>
<td>0.10</td>
</tr>
<tr>
<td>Haematocrit (%)</td>
<td>23</td>
<td>22</td>
</tr>
</tbody>
</table>

**FIGURE 1**

- DONOR™
- VS1
- Collection bag
- Self-levelling drip chamber

**FIGURE 2**

- Lipid droplet size distribution

**FIGURE 3**

- C3a reduction

**TABLE 1**

- Pre-Filtration: PLT = 56, RBC = 1.15, WBC = 0.9
- Post-Filtration: PLT = 56, RBC = 1.0, WBC = 0.9

**TABLE 2**

- Pre-Filtration: Total Hb = 4.7, Plasma Hb = 0.08, Haematocrit = 23
- Post-Filtration: Total Hb = 4.7, Plasma Hb = 0.10, Haematocrit = 22
Clinical results in 2001 – 2002 DONOR™ collection and replacement Vessels

Total number of systems followed clinically with protocol in various hospitals national and international (recorded until: September 19, 2002)

<table>
<thead>
<tr>
<th>Group 1)</th>
<th>Mean drainage time</th>
<th>Mean post drainage volume</th>
<th>Mean volume reinfused</th>
<th>Mean reinfusion time</th>
<th>Mean Aspiration volume replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total knee replacement n=186</td>
<td>04:00 hrs</td>
<td>490 mL</td>
<td>458 mL</td>
<td>01:31 hrs</td>
<td>347 mL</td>
</tr>
<tr>
<td>Group 2)</td>
<td>04:06 hrs</td>
<td>373 mL</td>
<td>359 mL</td>
<td>01:08 hrs</td>
<td>329 mL</td>
</tr>
<tr>
<td>Total hip replacement n=48</td>
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<td>366 mL</td>
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<td>Group 4)</td>
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<td>474 mL</td>
<td>383 mL</td>
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<td>Revision knee n=5</td>
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<tr>
<td>Group 5)</td>
<td>03:50 hrs</td>
<td>450 mL</td>
<td>435 mL</td>
<td>00:45 hrs</td>
<td>100 mL</td>
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<td>Uni knee n=2</td>
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<tr>
<td>Group 6)</td>
<td>03:47 hrs</td>
<td>446 mL</td>
<td>418 mL</td>
<td>01:12 hrs</td>
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<td>Spinal n=10</td>
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<tr>
<td>Group 7)</td>
<td>05:08 hrs</td>
<td>254 mL</td>
<td>224 mL</td>
<td>00:36 hrs</td>
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<td>Other n=5</td>
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<tr>
<td>Total n= 265</td>
<td>3:39 hrs</td>
<td>458 mL</td>
<td>428 mL</td>
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<td>322 mL</td>
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Total mean system recovery: 93.25 %

(\% volume reinfused of volume drained)

Total volume drained: 121.470 mL

Total volume reinfused: 113.430 mL

Savings in volume no. Packed Cells (300mL): 378,1

Total number of systems represented in graphs: n=265

Temperature was measured at start drainage, at start reinfusion and 2 hours after reinfusion. The measurements were taken over 126 DONOR™ systems.

The mean temperature change was 0.908730159 degrees Celsius. The mean range in which the temperature was measured varied between 35.89516129 and 36.78467742 degrees Celsius.

The group other, n=5 represents 1 bi-lat tramflap, 1 commando ENT and 1 cranio-facial reconstruction (on a 3 year-old girl)

Filterspecs: Leukocyte reduction: >81%, Fat reduction: 96%-100%, C3a reduction: 40%, Hemolysis: <0,04 (EU hem. guideline=0,8).

Abbreviations of the countries, participating in the DONOR™ protocol:

AL=Australia (6 hospitals)
B=Belgium (4 hospitals)*
It.=Italy (XX hospitals)*
Fi=Finland (1 hospital)*
HK=Hong Kong (4 hospitals)*
NZ=New Zealand (9 hospitals)*
NL=The Netherlands (36 hospitals)*
Sa=South Africa (35 hospitals)*
Si=Singapore (2 hospitals)*
*No of hospitals working with DONOR™ per country.

Five university hospitals are included conducting long term studies.

Three additional studies are conducted with local hospitals and Sanquin (Dutch association of Blood Banks).
Introduction

The DONOR™ re-infusion system is a constant vacuum, closed wound drainage system, consisting of:

- 800 mL chlorine free pre-evacuated collection container
- vacuum regulator
- connector tube with slide clamp and anti-reflux valve and connector
- air vent with 0.2 µm hydrophobic membrane filter and breakaway
- integrated injection port
- scalpeltipped trocar with pre-attached wound drains
- 600 mL pre-evacuated replacement collection container

and is indicated for drainage of blood from wounds and body cavities with subsequent filtration and re-infusion using the PALL LipiGuard VS Filter Set.

The following investigation was performed to demonstrate that clinically significant haemolysis is not caused during the aspiration process. A total of 10 DONOR™ collection and replacement vessels were tested.

Materials and Methods

NB. Testing was performed according to ANSI/AAMI AT6-19911 section 4.1.3 K1, K5, K6 and K7, with the exception that whole blood (WB) was aspirated directly from the donor bag (at room temperature).

- Test Blood
  1-2 day old, allogeneic, non-leucodepleted WB, with a haemoglobin content of 12g ± 2g/100mL. Blood age and temperature was recorded.

WB unit was sampled, volume recorded and analysis performed for plasma haemoglobin (Hb, see determination section) and full blood count (FBC – using a Sysmex K1000 automated cell analyser, Milton Keynes, UK).

WB unit was weighed after sampling and aspiration, and the collection system was weighed before and after aspiration.

WB unit was aspirated into the collection vessel according to the manufacturer’s instructions for use, the volume was recorded and sample analysis was performed.

Time taken for expression to complete was recorded, and the system left static for 6 hours before mixing well and taking final samples.

- Plasma Haemoglobin Determination
  Hb has a characteristic absorption density at 576nm although the presence of bilirubin and other pigments does not give a true representative result. Measurement of optical density at 560nm, 576nm and 592nm allows for correction of this non-specific absorption.

Sample Preparation

Samples were centrifuged at 1141g, 22°C for 10 minutes. The supernatant was carefully removed and placed into a clean plastic test tube. Samples were centrifuged again as above and the supernatant transferred to a clean plastic test-tube.

Sample Analysis

The spectrophotometer was blanked with phosphate buffered saline and optical densities (OD) were read at 576, 560 and 592nm.

A single OD was calculated using the formula 2y-(x+z) to calculate a reading where y=576nm, x=560nm and z=592nm, and the free plasma Hb concentration was determined from a standard curve.

Results

Mean flow-rate, as shown in Table 1, was 216-220 mL/min for the replacement and collection vessels respectively, with no flow-restrictors in the tubing.

Plasma Hb data, pre and post aspiration, for the collection and replacement vessels are shown in Table 2 and 3 respectively. There was no clinically significant Hb increase following aspiration either immediately, or after 6 hours static hold. Mean plasma Hb was <7.0mg/dL (<0.05 mMol/L) and % haemolysis was below 0.8% of red cell mass.

Discussion

Section 4.1.3 of ANSI/AAMI AT6-19911 states that in view of the number of variables likely to be encountered in a clinical situation, the manufacturer cannot be expected to make precise claims as to aspiration and re-infusion capacities of the device under the conditions of use. Any testing should reflect maximum pressures (or vacuum) and include all the relevant components of the system. Under these conditions, there was no significant increase in haemolysis of aspirated components when using the DONOR™ collection or replacement vessels.

The Guide to the Preparation, Use and Quality Assurance of Blood Components2 requires haemolysis to be <0.8% of red cell mass at the end of storage. Although this guideline does not directly apply to autologous donations, it is interesting to note that, under the test conditions described in this report, the DONOR™ System complies to these stringent specifications.

References

1. Association for the Advancement of Medical Instrumentation ANSI/AAMI AT6, Autologous Transfusion Devices 2nd Ed 1991
Table 1: Flow Rates – DONORTM Collection and Replacement Vessels

<table>
<thead>
<tr>
<th>Sample No</th>
<th>Collection vessel</th>
<th>Post-aspiration volume (mL)</th>
<th>Aspiration time (min)</th>
<th>Mean flow-rate (mL/min)</th>
<th>Replacement vessel</th>
<th>Post-aspiration volume (mL)</th>
<th>Aspiration time (min)</th>
<th>Mean flow-rate (mL/min)</th>
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<td>425</td>
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Mean 435 2:00 220

Table 2: Plasma Haemoglobin – DONORTM Collection Vessel

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<th>Sample No</th>
<th>Age of blood (days)</th>
<th>Pre-aspiration</th>
<th>% Haemolysis</th>
<th>Post-aspiration</th>
<th>% Haemolysis</th>
<th>Post-aspiration (6 hr hold)</th>
<th>% Haemolysis</th>
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<td>(mg/dL)</td>
<td>(mMol/dL)</td>
<td>(mg/dL)</td>
<td>(mMol/dL)</td>
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Mean <7.3 <0.05 <0.04 <5.8 <0.04 <0.03 <6.0 <0.04 <0.03

Table 3: Plasma Haemoglobin – DONORTM Replacement Vessel

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<th>Pre-aspiration</th>
<th>% Haemolysis</th>
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<th>% Haemolysis</th>
<th>Post-aspiration (6 hr hold)</th>
<th>% Haemolysis</th>
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<td>(mMol/dL)</td>
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Mean 2 <5.8 <0.04 <5.8 <0.04 6.8 <0.05 <0.04

DONORTM is a concept of Van Straten Medical concept with the use of exclusive Pall technology.

Manufactured by Medinorm AG, Germany
SAFE BLOOD RECOVERY

+ SAFE BLOOD REINFUSION

= THE DONOR™ SYSTEM

Summary

The unique DONOR™ Pre-Evacuated Post-Operative Autologous Blood Reinfusion System provides a safe and user-friendly option for utilizing a patient’s wound drained blood, leading to a reduction in the usage of allogeneic blood products, their associated risks and costs.

References

8. Berman et al., Comparison between intermittent (spring loaded) and continuous closed suction drainage of orthopaedic wounds: a controlled clinical trial. Orthopedics, 13(9):1059-64.1990
9. Heissel et al., Wound drainage with a continuous high vacuum drainage system and a drainage system with variable vacuum. Urtaburger, 96(3):522-5.1996

DONOR® is a concept of Van Straten Medical concept with the use of exclusive Pall technology.
DONOR™ is a concept of Van Straten Medical with the use of exclusive Pall filter technology. Manufactured by Medinorm AG.