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**BLOOD SAFETY**

Tuesday, June 5th 2018

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BLOOD SAFETY

ISBT Toronto 2018 ● Tuesday, June 5th 2018 ● 12.00 - 1.30 PM
Room 718 B

• Chairperson
Prof. Dana Devine CBS, Vancouver

• Presentations
« THERAFLEX UV-Platelets: Mechanism of action, specifications and sterility studies »
Prof. Axel Seltsam (DRK, Springe)

« The phase III CAPTURE Trial: routine use in the blood bank of Frankfurt »
Dr. Veronika Brixner (DRK, Frankfurt)

« Review on the inactivation of arboviruses with THERAFLEX »
Prof. Denese Marks (ARCBS, Sydney)
SELECTED PUBLICATIONS:

Devine DV. Pathogen inactivation strategies to improve blood safety: let’s not throw pathogen-reduced platelets out with their bath water. JAMA Oncol, 2018; 4(9):1007-1008. DOI: 10.1001/jamaoncol.2017.4949


Associate Professor for Transfusion Medicine,
Hanover Medical School, Germany

Head of production and head of R&D,
German Red Cross Blood Service NSTOB, Springe

**EMPLOYMENT HISTORY**

2008 - present: Head of production and head of R&D
German Red Cross Blood Service NSTOB, Springe

2003 - 2008: Associate Professor for Molecular Immunohaematology
Institute of Transfusion Medicine, Hannover Medical School, Germany

2001 - 2003: Resident physician and scientific assistant
Institute of Transfusion Medicine, Hannover Medical School, Germany

1998 - 2001: Scientific assistant
Institute of Transfusion Medicine, University Hospital Charité
Berlin, Germany

1996 - 1998: Junior physician
Medical Clinic I of the Clinical Centre Fürth, teaching hospital of the Friedrich-Alexander University Erlangen-Nuremberg

**EDUCATION**

2010: Master of Health Business Administration (MHBA)
Friedrich-Alexander University Erlangen-Nuremberg

2002: Specialist in Transfusion Medicine

1996: Doctor of Medicine
Friedrich-Alexander University Erlangen-Nuremberg, Germany

**THERAFLEX UV-PLATELETS: AN UPDATE ON THE CLINICAL DEVELOPMENT**

In line with current microbial risk reduction efforts, pathogen inactivation (PI) technologies for blood components promise to reduce the residual risk of known and emerging infectious agents. THERAFLEX UV-Platelets is a novel UVC-based PI technology for treatment of platelet concentrates (PCs) that works without photoactive substances. It is the product of a joint venture between Macopharma and the German Red Cross Blood Service NSTOB in Springe, Germany. Shortwave UVC light (254 nm) directly interacts with nucleic acids to form pyrimidine dimers that block the elongation of nucleic acid. UVC irradiation mainly affects the nucleic acids of pathogens and leukocytes and does not impair plasma and platelet quality. The THERAFLEX UV-Platelets system effectively inactivates a broad range of different disease-causing viruses, bacteria and protozoa. As no photoactive substances are involved, UVC treatment is just as simple but faster (takes less than 1 minute) than gamma irradiation, and can easily be integrated into the manufacturing processes at blood banks.

The THERAFLEX UV-Platelets system is currently under clinical investigation in a multicenter trial in Germany. This phase III, randomized, controlled, double blind study, called CAPTURE, investigates the clinically effectiveness and safety of UVC-treated PCs in comparison to conventional (non-UVC-treated) PCs. Both, buffy-coat-derived pool PCs and apheresis PCs stored for up to 5 days in platelet additive solution (SSP+), are used in the study. Hematology-oncology patients with thrombocytopenia are randomly assigned to receive prophylactic and therapeutic transfusions (either UVC-treated or control platelets). Primary endpoint of the study is 1-hour corrected count increment (CCI). Secondary endpoints include efficacy-related parameters (24-hour CCI, 1-hour and 24-hour CCI, transfusion requirement of red cells and platelets, platelet transfusion interval) and safety parameters (e.g., severe bleeding and platelet refractoriness). The ongoing study started in 2016. Patients will be enrolled up to a maximum of 166 patients.
Selected publications:


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**DR. VERONIKA BRIXNER**

**Speaker**

**The phase III CAPTURE Trial: routine use in the blood bank of Frankfurt**

**Head of production**

German Red Cross Blood Service Baden-Württemberg - Hesse, Frankfurt

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**EMPLOYMENT HISTORY**

2017 - present:
Head of production
German Red Cross Blood Service Baden-Württemberg - Hesse, Frankfurt

2002 – 2010:
Resident physician and scientific assistant
German Red Cross Blood Service Baden-Württemberg - Hesse, Frankfurt

2000 – 2001:
Junior physician
Medical Clinic I of the St. Joseph's Hospital Wesbaden, teaching hospital of the Johann Wolfgang Goethe University, Frankfurt, Germany

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**EDUCATION**

2016:
Master of Science in Clinical Trial Management
Beuth University of Applied Science , Berlin, Germany

2010:
Specialist in Transfusion Medicine

2002:
Doctor of Medicine
Johann-Wolfgang Goethe University, Frankfurt, Germany
Improvements in donor selection, infectious disease testing, and donor deferral policies have effectively reduced but not eliminated the risk of transfusion-transmitted infectious diseases. Prevention of transfusion transmitted infection and, at the same time, preservation of cell vitality are core objectives for pathogen inactivation methods for blood products. Pathogen reduction technology may enhance microbial safety of platelet transfusion by reducing bacterial and viral contamination.

We established the manufacturing of UVC-treated pooled platelet concentrates (PPCs) and UVC-treated apheresis platelet concentrates (APCs) under routine conditions using the THERAFLEX UV-Platelets method. Both UVC-treated and non UVC treated PPCs and APCs, have been used as clinical investigational products for the CAPTURE (Clinical Assessment of Platelets Treated with UVC in Relation to Established Preparations) clinical trial.

UVC treated PPCs were produced within the routine production area using 5 buffy coats and 280 ml SSP+ additive solution. There was no need to adapt the separation conditions for the manufacturing of the UVC treated PPCs. Total protein concentration and platelet concentration were analyzed prior UVC treatment for all UVC treated PPCs. Every process step was documented using our standard Blood Bank software. We produced more than 650 UVC treated PPCs. Batch size was 2-10 PPCs per run. Tests for bacterial contamination were negative for all tested PPCs (n = 120).

Due to the modest hands-on time and the lack of an incubation time integration of UVC treatment for platelets into routine production was easily possible.

Selected publications:

Prof. Denese Marks  
« Review on the inactivation of arboviruses with THERAFLEX »

VIRAL INACTIVATION WITH THERAFLEX MB-PLASMA AND THERAFLEX UV-PLATELETS SYSTEMS

Many arthropod-borne viruses have emerged as threats to the safe supply of blood. These include dengue virus (DENV), chikungunya (CHIKV), Ross River virus (RRV), which has been reported across Australia and the Pacific, and more recently, Zika virus (Zika) and yellow fever virus (YFV). One approach to manage the risk of transfusion-transmission of these viruses could be the use of pathogen inactivation technologies (PI), such as the THERAFLEX MB-Plasma system and THERAFLEX UV-Platelets system.

We have examined the ability of these systems to inactivate DENV strains, CHIKV, RRV, Zika and YFV in platelets and plasma. The level of viral infectivity was determined using a modified version of a conventional plaque assay and the reduction in viral infectivity was calculated. Findings from our studies will be reported.
Selected publications:

Fryk JJ, Marks DC, Holohan-Petters J, Prow NA, Watterson D, Hall RA, Young PR, Reichenberg S, Sumian C, Faddy HA. Dengue and chikungunya viruses in plasma are effectively inactivated after treatment with methylene blue and visible light. Transfusion 2016; 56: 2278-2285.


Loh YS, Johnson L, Kwok M, Marks DC. Pathogen reduction treatment alters the immunomodulatory capacity of buffy-coat derived platelet concentrates. Transfusion 2014; 54: 577-584

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