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Proof of Concept for Ozone-Based Disinfection of Heater Cooler Units

Elimination of bacteria in water circulation systems of HCUs with ozone

Abstract: Heater Cooler Units (HCUs) are frequently used not only during heart surgery but also in ECMO therapy to regulate the blood temperature of patients. It is known from cardiac surgery that the water circuits of HCUs can be bacterially contaminated and under adverse conditions can lead to a nosocomial infection of the patient.

The addition of chemical disinfectants to the water of HCUs is problematic. In addition, it is an increasingly significant cost factor due to the required material and personnel input.

The aim of this research project is both the development of an automated device for disinfecting water in HCUs and proof of its effectiveness. The device is based on ozone, a substance with known antimicrobial properties. To prevent ozone from coming into contact with the HCU components, the water is irradiated with UV light (254nm). Two bypasses and ozone sensors guarantee a complete elimination of residual ozone. The effectiveness of the device was tested by series of experiments with the surrogate germ, *Pseudomonas aeruginosa*.

The device allows a wide range of ozone concentrations and exposure times to be selected. In previous test series, it has been shown both that a reduction of the bacterial count to drinking water quality can be achieved with a treatment time of only one hour, and that self-cleaning can be carried out effectively before clinical use, and in standby mode.

Attention must be paid to the water quality in HCUs as a potential source of infection, regardless of where they are used. The "proof of concept" showed an excellent disinfection effect with simultaneous elimination of excess ozone to drinking water levels. The number of indicator bacteria in the water tank of the dummy HCU was reduced by approx. 98% after only 30 minutes.

Keywords: Heater Cooler Unit, Disinfection, Ozone, ECMO, *Mycobacterium chimaera*, Computational Fluid Dynamics, Experimental rig "O_3Desi"

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1 Objective

Heater-Cooler Units (HCUs) are widely used in ECMO therapy to regulate patients' blood temperature. The HCU consists of a water circuit passing through a heat exchanger also connected to the patient's blood supply. In addition, ventilator fans in the HCU remove heat produced by the cooling unit, the pumps and electronics in close proximity immune-compromised patients. This poses a potential problem since HCU water can quickly become contaminated with bacteria, algae and fungi [1].

The focus was particularly on the contamination of Heater-Cooler Units with *Mycobacterium chimaera*, which cannot be completely avoided even with current disinfection measures. Since 2014, cases have been described in which patients were infected with *Mycobacterium chimaera*. All patients have in common that they have undergone heart surgery using a Heater-Cooler Unit. This means that there is not only a problem of contamination of the water in the HCU, but also an extremely high risk of disease in patients who have been operated on using a HCU [2]; [3]; [4].

For this reason, both the German Federal Ministry for Drugs and Medical Devices (BfArM) and the U.S. Food and Drug Administration (FDA) have issued recommendations for the handling of Heater-Cooler Units [5]. In addition, the German Society for Cardiovascular Engineering (DGfK) is calling for a practical solution to this hygiene problem of HCUs.

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The addition of chemical disinfectants to HCU water is problematic. The development of an ozone-based disinfection device specifically for HCUs provides a system for the effective disinfection of circulating water.

2 Methods

The aim of this state-funded research project was to develop a proof of concept for the automatic disinfection of circulating water in HCUs (see Figure 1). The reduction of bacteria in a reaction chamber was mapped by numerical flow simulation to show disinfection efficacy and optimize the design of the disinfection unit for HCU water.

Figure 1: Experimental rig "O_3Desi"

The device includes a static mixer, and uses ozone, a well-known antimicrobial agent, as disinfectant. To prevent ozone from coming into contact with the components of the HCU (metals, plastics), its circulating water is irradiated with UV light (254 nm). Two bypasses and ozone sensors guarantee the elimination of any residual ozone. In addition, the disinfection device can also be used disconnected from the HCU using surge ozonisation. The efficiency of the device was tested by series using *Pseudomonas aeruginosa* bacteria as a surrogate germ.

3 Results

The device allows the selection of a wide range of ozone concentrations and exposure times. Disinfection efficacy was tested at the Clinic for Heart and Thoracic Surgery, University Hospital Bergmannsheil, Bochum, Germany. Bacterial cultures were added sterile water and filled into the disinfection device.

To date, tests have shown that a reduction in bacteria to a level consistent drinking water was possible within an hour.

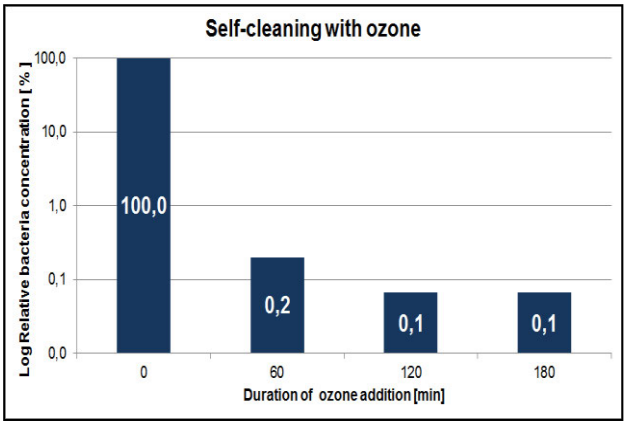

Figure 2: Bacteria elimination during self-cleaning

The Figure 2 above shows the result of the self-cleaning routine with ozone. All measurement results are shown in the diagram logarithmically in percent. The diagram of the bacteria reduction at sampling point is located in the Figure 3.

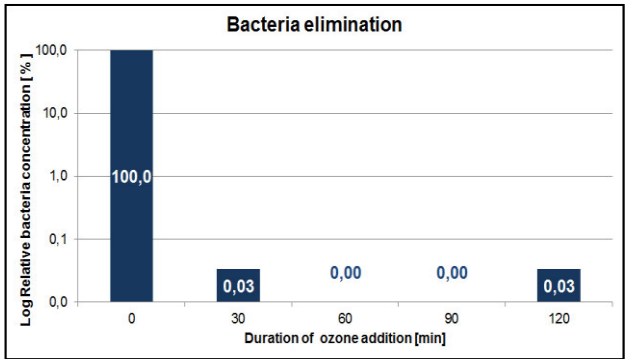

Figure 3: Bacteria elimination at sampling point

Both figures show the representative elimination of bacteria after a treatment time of 1-3 hours with ozone.

4 Conclusion

To date, little attention has been paid to water quality in HCUs, which are mainly used in heart-lung machines but also in ECMO therapy. When used, these devices represent a potential source of infection in the operating room or intensive care units. The "proof-of-concept" showed an excellent disinfection effect and simultaneous elimination of excess ozone.

The diagram in Figure 4 shows that the number of indicator bacteria in the water tank of the dummy HCU has already been reduced by approx. 98% after 30 minutes. Further

experiments with a longer lasting disinfection are currently in progress.

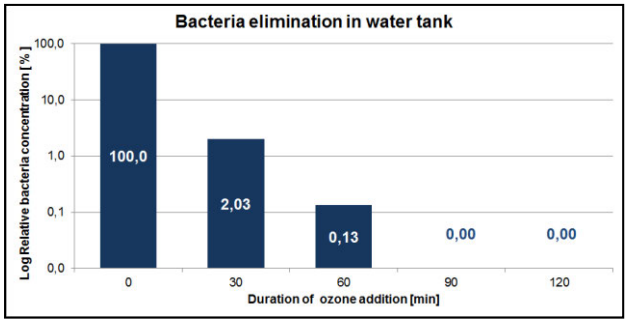

Figure 4: Bacteria elimination in Dummy-HCU (water tank)

This lays the foundation for the development of a prototype, which is to be designed as a user-friendly auxiliary device for ECMO-HCUs.

Author Statement

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