"Scientific study to verify the effect of hot water disinfection for the prevention of biofilm formation in loop piping systems with an innovative Hygiene Monitor"

Dialysis water in loop piping systems (permeate) can be contaminated by numerous chemical or microbiological factors [1]. Dialysis water of suboptimal quality leads to a potential hazard for patients. Over the last few years an improvement in the chemical and microbiological quality of dialysis water has been achieved step by step due to progress in water treatment, advancements in piping and disinfection systems, and improvements in national regulatory dialysis standards [2, 3]. However, with current routine methods it is only possible to detect potential microbiological contamination of the piping systems above defined method thresholds. Also, numerous bacterial strains are known which can survive in the oligotrophic environment of dialysis water but often cannot be cultivated on standard culture media [4]. Additional efforts are therefore required to improve the possibility of detecting microbiological contamination of the loop piping system, inter alia, at an early stage.

Many dialysis providers nowadays use modern disinfection systems with hot water disinfection. Depending on the provider, disinfection cycles from once a week to 6 times a week are reported. The relevant recommendations regarding disinfection frequency per week to maintain a sterile loop piping system have not yet been investigated adequately. By means of an innovative Hygiene Monitor developed at the "Institute for Hygiene and Public Health at the University of Bonn" the effect of hot water disinfections 1-3 times a week was therefore investigated at 3 different dialysis centres.

Study methodology
At 3 centres, water treatment systems of the manufacturer DWA were used, each of which consisted of reverse osmosis, dialysis water loop piping made of PE-Xa and a hot disinfection system with integrated ultrafiltration (type: nephro SAFE). The blank control used was a facility without a hot water disinfection system. For the investigation, sterile silicone tubes were connected to the end of the loop piping system by means of a Hygiene Monitor (Fig. 1). Retrograde permeate flow from the tubing system into the loop piping, e.g. due to pressure fluctuations in the system, was ruled out by means of a non-return valve.

In 4 different loop piping systems at 3 dialysis centres, hot water disinfection procedures did not take place at all or took place once a week, twice a week or three times a week at a temperature of 83°C for 1 hour. The prospective study lasted 8 months. After 2, 6 and 8 months in each case, parts of the sterile silicone tube were tested for the onset of biofilm formation by draining dialysis water, using a standardised method. The number of colony-forming units (CFU/cm2) and the total cell count (TCC/cm2) were determined and the tubes were examined under a scanning electron microscope (SEM) in order to visualise potential biofilm residues on the tube surface, within the scope of a standardised process.

Table 1: Overview of the results of determining CFU (colony-forming units) and TCC (total cell count) by centre and investigation period. Hot water disinfection performed twice a week (HWD) at 83°C for 1 h ensures a contamination-free tubing system without biofilm formation (n.d. = not detectable). The blank control in an old loop piping system without the option of HWD, on the other hand, showed a continuous rise in CFU and TCC.
Results
In cases where no disinfection took place, the investigation revealed rapid contamination with progressive biofilm formation by the dialysis water of the old contaminated loop piping system (location A).
In an SEM examination, hot water disinfection performed only once a week at 83°C for 1 h showed proof of microbiological particle residues and potentially viable microorganisms indicating the onset of biofilm formation. The bioburden in the microbiological tests remained below the limit of detection (location B). From 2 disinfections per week upwards only particles or matrix residues were detected (locations C and D) (Fig. 2).

Conclusion
The prospective, scientific study presented here using an innovative Hygiene Monitor has shown that a single hot water rinse at 83°C for 1 h within one week can keep colonisation by microorganisms in an initially sterile silicone tube below the limit of detection. From 2 rinses upwards the SEM images of the silicone tubing surfaces tested showed no significant occurrence of potentially viable microorganisms on the surface. From 3 hot water rinses per week it was no longer possible to detect any amorphous particle residues on the surface of the tubing.

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Literature sources