Sebastian Buhl, Carina Werner and Clemens Bulitta*

Standard manual reprocessing of angiographic systems in the hybrid OR

Abstract: A current FDA guidance demands the validation of cleaning and disinfecting protocols even for non-sterile medical devices. The aim of this work is to clarify whether this is already possible using the guidance itself as well as the German DIN EN ISO 17664. An angiography system (Artis Zeego / Pheno - Siemens) was selected as a test object for the validation of a cleaning and disinfection protocol for medical devices in a hybrid operating room. In pilot study prior to the trial, critical points of the system were evaluated by means of questionnaires to clinical users (OTA, surgical technicians). An initial assessment of the in-house cleaning protocols used in the hospitals was done by using a fluorescence assay. The microbiological examination took place subsequently by contact plates and swabbing to determine the amount and type of germs on the surfaces of the system. These experiments were done at three different clinical sites. It was found that there was a significant germ count on several surfaces of the product even after in-house cleaning and disinfection (C&D). After application of an enhanced C&D plan, these germs could be greatly reduced at all verified sites. In addition, it could be shown that DIN EN ISO 17664 can in principle be applied to non-sterile medical products.

Keywords: angiographic system, cleaning and disinfection protocol, validation

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1 Introduction

The procedure for cleaning and disinfection or sterilization is defined in-depth and mandatory for sterile used medical products. [2] This has not yet been the case for non-sterile used medical devices. These include e.g. also angiography systems in hybrid operating rooms (hybrid surgery). The Food and Drug Administration (FDA) is now demanding for the first time in one of its guidelines to validate also cleaning and disinfecting instructions for non-sterile medical products. [1] The inadequate cleaning of medical products is a possible source of infection for medical personnel and patients. This risk of infection by contaminated surfaces has already been showed by other publications. [4-6] A validated protocol for the processing of these non-sterile medical products is therefore an important step to minimize infection risks and to improve the hygienic situation in clinical environments.

2 Material and methods

A first evaluation of the hygienic situation in the participating hospitals was done via a survey of the personnel. The questionnaire for the clinical users of the angiography systems included questions on the cleaning and disinfection of the systems as well as an assessment of the critical surfaces. In this manner focus points could be defined. As a second step a fluorescence test was performed on the systems. With the GlowCheck test ultraviolet light (UV light) visually checks whether cleaning and disinfecting measures have taken place at specifically defined critical points of the systems. [7] Using this test kit, the angiography system was contaminated and then cleaned to obtain an initial assessment of the in-house cleaning and disinfecting procedures. After that, the effectiveness of the C&D procedures was examined microbiologically. For this purpose, samples were taken before and after C&D measures at 36 high risk sampling points (monitors, joysticks, C-arms, control elements, etc.) and these were incubated for 72 hours at 35 ° C. This process was then repeated with a revised and improved C&D plan that was elaborated by our working group based on the FDA Guidance and the DIN EN ISO 17664. The germ growth was documented and evaluated quantitatively. In addition, gram-negative germs were differentiated by selection media (McConkey II agar). In order to be able to identify the pathogenic potential precisely an identification and resistance determination was done for the gram-negative bacteria using the Vitek2 system. Finally two systems in clinical use were

***Corresponding author: Prof. Dr. Clemens Bulitta:** Technical University of Applied Science Amberg-Weiden, Hetzenrichter Weg 15 , Germany, e-mail: c.bulitta@oth-aw.de, +49 (961) 382-1620, +49 (961) 382-2620

Sebastian Buhl, Carina Werner: Technical University of Applied Science Amberg-Weiden, Hetzenrichter Weg 15 , Germany

used to assess and validate the newly defined and improved C&D procedure.

3 Results

The evaluation of the critical surfaces of the angiographic systems revealed the operating table, the control elements and the C-arm as highly critical (Figure 1).

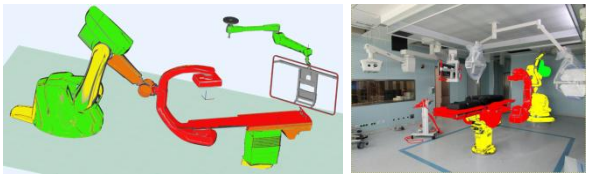

Figure 1: critical surfaces of the angiographic system (from red: very high to green: low)

When considering the in-house C&D procedures, it could be determined that these were mostly not adapted to the requirements of a hybrid operating theatre. We could demonstrate a significant contamination on several surfaces of the systems even after the in-house cleaning and disinfection measures (>10 CFU/25cm²). (Figure 2)

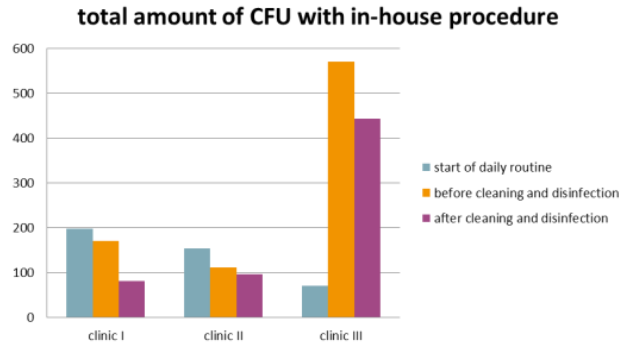

Figure 2: Microbiological burden of angiographic systems with in-house cleaning procedures

The operating unit for the angiography system as well as the mounting rail of the table top are noticeable. Due to their high microbial burden before C&D, they are classified as particularly critical. High values of microbiological contamination before cleaning and disinfection were also found in the suspension system of the monitor display, the C-arm and the robot cover. Based on the values according to C&D, high numbers of germs were found mainly on the mattress and the C-arm. In the evaluation of 214 samples before C&D, a total of 29 samples exceeded the threshold of 10 CFU/25cm² (13.5%). From 107 samples taken in the three clinics, according to the company's own C&D measures, 16 were above the threshold (15%). After introducing the optimized C&D procedure, none of the samples had a value above 10 CFU/25cm² (Figure 3).

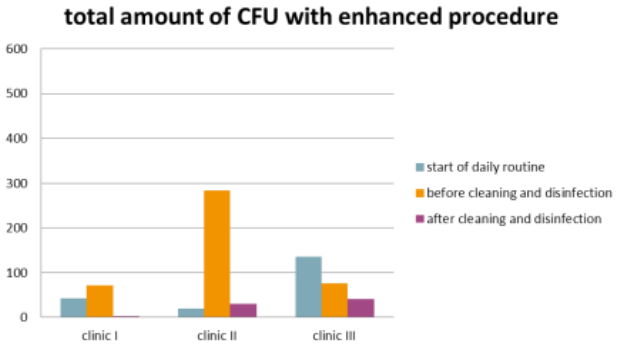

Figure 3: Microbiological contamination with optimized cleaning procedures

Looking at the procedure of all observed C&D, it can be seen that they do not follow a defined sequence for the most part. The objects are cleaned in no particular order and no particular division of the cleaning personnel is allocated to perform the C&D task. The duration of C&D is hardly comparable within a hospital. Whether the angiography device is also cleaned when it is not used is not defined in the procedures. In addition, the cleaning personnel often were not informed whether the system was in use.

The evaluation of the pathogens found to a large extent gram-positive germs (Staphylococcus, Micrococcus). Through differentiation media, however, some facultative pathogenic gram-negative pathogens could also be isolated (Figure 4).

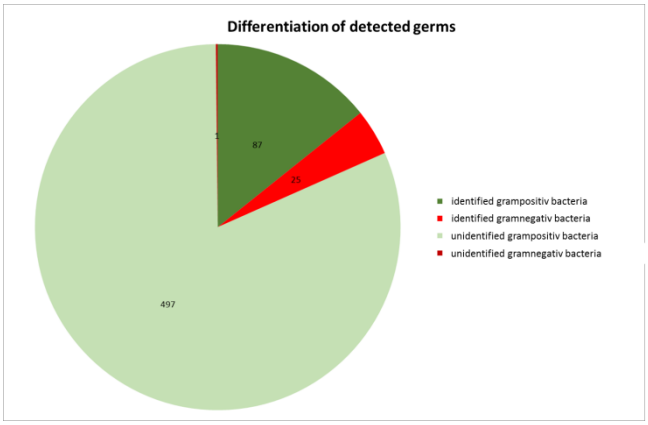

Figure 4: Distribution of measured bacterial contamination

A review of these bacteria by the Vitek2 system revealed a broad spectrum of facultative pathogens (Pseudomonas, Acinetobacter). No multi-resistant pathogens (MRSA, MRGN) were detected in the resistance test.

Further assessments included clinical validation of the improved C&D procedure on installed and clinically used systems. It could be shown that with the procedure these systems all showed ≤ 2 CFU/25cm^2. This showed the excellent effectiveness of the procedure.

4 Discussion

Hitherto even after in-house C&D measures a potential infection risk for the patient is to be expected. This can be seen in both the partly high number of germs on certain surfaces, as well as the detected pathogens. With the introduction of the enhanced cleaning concept, the germ count could be significantly reduced after cleaning the system (<10 CFU/25cm²). Based on the results so far, both the FDA Guidance and the DIN EN ISO 17664 can be used in part as a validation basis for non-sterile medical devices, especially for an angiography system. The DIN EN ISO 17664 can already be implemented by means of some modifications or additions in the existing C&D plans. For the validation according to the FDA Guidance, however, the different test methods still need to be better described and established. Ideally a similar standard like the DIN EN ISO 17664 should be developed.

Even if the validated C&D plan is not mandatory today we suggest applying it in order to standardize cleaning and disinfection procedures.

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Author's Statement

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