

Key Words

- instrument reprocessing
- foam cleaner
- material compatibility
- pre-treatment

Analysis of Stainless Steel and Anodized Aluminium Material Compatibility with Foam Sprays Used for Keeping Used Surgical Instruments Moist

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The material compatibility of four ready-to-use enzymatic foam cleaners on anodized aluminium and stainless steel was studied. This type of cleaner is applied in operating theatres to prevent bio-burden from drying on used surgical instruments. Cleaners were applied for one exposure time to test materials alone and in combination with blood. The study shows no or slight changes on the tested materials when contacted with most of the cleaners. Pitting corrosion was detected with one cleaner at extended contact time. This effect could be caused by the high chloride content in the product.

Introduction

Foam sprays or other ready-to-use cleaning solutions are recommended in the guidelines of some countries to prevent bio-burden from drying onto the surface of surgical instruments during the transport from the point-of-use to the central sterilisation unit (1). This study investigates the effects of this procedure on the maintenance of surgical instruments and containers. Four commercially available foam sprays were tested for their compatibility with stainless steel test pieces (covering different steel compositions and surface structures) and with anodized aluminium test pieces. Furthermore, influences of blood alone and in combination with the foam cleaner on the surface of the test pieces were assessed for one exposure time.

Material and methods

Study products

The following enzymatic foam sprays which are indicated for use to prevent soil drying on surgical instruments were employed (ingredients are mentioned according to supplier information). Chloride ion concentration and pH value were detected for all cleaners.

- Cleaner 1, containing quaternary ammonium propionate, polyhexamethylene biguanide hydrochloride, non-ionic and cationic surface-active agents, enzymes, sequestering agents and stabilising agents.
- Cleaner 2, containing enzymes and surfactants.
- Cleaner 3, containing enzymes, nonylphenyl-polyethylene glycol and non-oxynol-9.
- Cleaner 4, containing enzymes and nonylphenyl-polyethylene glycol.
- Reference/soil, containing heparinised sheep's blood mixed with protamine sulphate.

Test pieces

Test pieces with dimension of 50 × 50 × 2 mm made from aluminium AlMg05, representative of material in transport containers, made from stainless steel X20Cr13, representative of non-cutting surgical instruments, and made by stainless steel X46Cr13, representative of cutting surgical instruments, were tested. The surface of the aluminium test pieces was colourless anodized. Surfaces

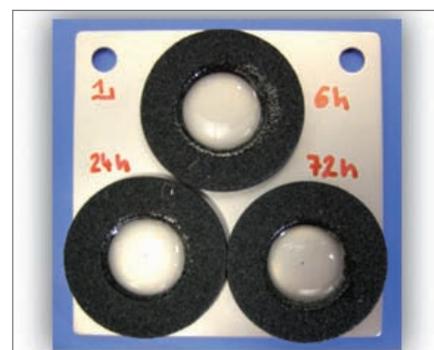


Fig. 1: Ring cell placement on test pieces

of stainless steel test pieces were treated with three different methods resulting increased surface roughness (brushed, bead blasted, grinded). Three ring cells with an inner circle of 13 mm made by H. Fischer GmbH, Sindelfingen, Germany, were fixed on each test piece to contour the test area (Figure 1).

Contact time

The contact times of the studied products on the material surfaces were defined to simulate the reprocessing timeframes

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used in one working day (contact time: 6 h), reprocessing overnight (contact time: 24 h) and reprocessing after a weekend (contact time: 72 h).

Experimental design

Test pieces made of stainless steel were cleaned under alkaline conditions and thermally disinfected in a washer disinfectant before each use. All test pieces were cleaned by wiping the surfaces with paper towels and methanol followed by the fixation of ring cells.

Cleaner, applied without foaming, (0.5 ml) or reference/soil B (0.2 ml) were applied in the ring cells. Furthermore mixtures of cleaner (0.5 ml) and references/soil (0.2 ml) were investigated.

Ring cells were removed after defined contact time and test pieces were rinsed with lukewarm water with low flow pressure for 30 seconds. If it was necessary, cleaning procedure was supported by wiping with paper towel under low pressure. Test pieces were dried with methanol and paper towels. The room temperature was $22\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ and the relative humidity in the room was $30\% \pm 5\%$ throughout the investigation.

Material changes in test pieces were observed by visual check and by using stereo microscope with six to ten times magnification.

Results

Cleaner analyses

All cleaners were measured as neutral or slight alkaline (Table 1). Significant differences between the cleaners were observed in respect to concentration on chloride ions. Cleaner 2 contained ten times higher concentration of chloride ions than cleaner 4, which had the lowest concentration.

Evaluation of moisturizing and rinsing behaviours

All investigated products kept the surfaces of test pieces moist up to of six hours (Table 2). At times greater than 6 hours, surfaces treated with cleaners 2, 3, and 4 were dry and cleaner 1 had a gelatine-like consistency.

Cleaners based on surfactants should be rinsed easily from the surface with lukewarm water and should facilitate the

Study product	Chloride ion concentration [mg/l]	pH-value
Cleaner 1	70	8.9
Cleaner 2	430	6.9
Cleaner 3	80	8.5
Cleaner 4	30	7.4

Table 1: Chloride ion concentration and pH-value of studied products

Study product	Drying behaviour			Rinsing behaviour
	6 h	24 h	72 h	
Cleaner 1	Wet	Gelatine like	Gelatine like	Moderate, mechanical support required
Cleaner 1 + blood	Wet	Gelatine like	Gelatine like	Moderate, mechanical support required
Cleaner 2	Wet	Dry	Dry	Very good
Cleaner 2 + blood	Wet	Dry	Dry	Very good
Cleaner 3	Wet	Dry	Dry	Good, slight mechanical support required
Cleaner 3 + blood	Wet	Dry	Dry	Good, slight mechanical support required
Cleaner 4	Wet	Dry	Dry	Good, slight mechanical support required
Cleaner 4 + blood	Wet	Dry	Dry	Good, slight mechanical support required

Table 2: Moisturizing and drying behaviours of studied products alone and in combination with blood versus time

remove of soils such as blood. These behaviours were observed completely just in the case of cleaner 2. Rinse behaviours of cleaner 3 and 4 alone and in combination with reference/soil was good but was better with the slight mechanical support of wiping with a paper towel. Removal of cleaner 1 from the surface was moderate. Considerable mechanical support was necessary to remove cleaner and soil from the surface at longer contact times than six hours.

Evaluation of material compatibility

No changes were observed on the surfaces of test pieces made of colourless

anodized aluminium (Table 3) or stainless steel X20Cr13 (Table 4) and stainless steel X46Cr13 (Table 5) with brushed surfaces after interaction with heparinised sheep's blood and foam cleaners alone or in combination of foam cleaner with blood at contact time up to 72 h. Test pieces made of both steel types with bead blasted surfaces showed no visible changes after interaction with most of the cleaners with exception of cleaner 2. This cleaner alone and in mixture with blood led to visual detectable brightening on bead blasted surfaces of both stainless steel types after six hour contact time. Pitting corrosion was observed at

extended contact between cleaner 2 and bead blasted surfaces of stainless steel X46Cr13 (Table 5). Mixtures of cleaner 2 and heparinised sheep's blood accelerated the incidence of this effect. Pitting corrosion was also detected on bead blasted surfaces of stainless steel pieces X20Cr13 after contact of 24 hours with a mixture of cleaner 2 with heparinised sheep's blood (Figure 2). Grinded surfaces on both types of stainless steel show pitting corrosion after interaction with cleaner 2 alone and in mixture with blood at contact time longer than six hours (Table 4 and Table 5).

Discussion

Besides hygienic aspects, like cleaning, disinfection and sterilisation, the importance of other elements, like long-term maintenance of instrument value and functionality, have to be considered with regard to instrument reprocessing. New or modified procedures or chemicals have to be evaluated in respect to their impact on all elements of the process.

Some guidelines for reprocessing of instruments recommend keeping soiled surgical instruments moist in order to reduce bio-burden adhesion while avoiding corrosion on metallic instruments (1).

Types of stainless steel used for manufacturing surgical instruments and their preferred application areas are described in standard EN ISO 7153-1 (2). Durability of stainless steel against environmental impacts, especially against chloride ions, depends on the steel composition as well as on the type of heat treatment and surface treatment. Increased carbon content at constant chromium level leads to higher corrosion sensitivity to chloride ions. An analogous correlation exists in respect to surface roughness, with brushed surfaces being more durable against corrosion causing substances than bead blasted or grinded surfaces.

Results of our investigation show the increased sensitivity of grinded surfaces for corrosion in the case of cleaner 2 in interaction with test pieces of both steel types at contact times longer than six hours. The objective of the present investigation was not to determine if the detected increased content of chloride ions in cleaner 2 or the total composition

Material		AlMg05 colourless anodized			
Contact time	Study product				
06 h	Blood	-			
24 h	Blood	-			
72 h	Blood	-			
Contact time	Study product	C1	C2	C3	C4
06 h	Cleaner	-	-	-	-
24 h	Cleaner	-	-	-	-
72 h	Cleaner	-	-	-	-
06 h	Cleaner + blood	-	-	-	-
24 h	Cleaner + blood	-	-	-	-
72 h	Cleaner + blood	-	-	-	-

Table 3: Surface changes on anodized aluminium caused by interaction with blood, studied products alone and by combinations of studied products with blood versus on contact time

(-) no change, (#) visual changes, (+) pitting corrosion

Material		X20Cr13 brushed				X20Cr13 bead blasted				X20Cr13 grinded			
Contact time	Study product												
06 h	Blood	-				-				-			
24 h	Blood	-				-				-			
72 h	Blood	-				-				-			
Contact time	Study product	C1	C2	C3	C4	C1	C2	C3	C4	C1	C2	C3	C4
06 h	Cleaner	-	-	-	-	-	#	-	-	-	-	-	-
24 h	Cleaner	-	-	-	-	-	#	-	-	-	+	-	-
72 h	Cleaner	-	-	-	-	-	#	-	-	-	+	-	-
06 h	Cleaner + blood	-	-	-	-	-	#	-	-	-	-	-	-
24 h	Cleaner + blood	-	-	-	-	-	#	-	-	-	+	-	-
72 h	Cleaner + blood	-	-	-	-	-	#+	-	-	-	+	-	-

Table 4: Surface changes on stainless steel X20Cr13 caused by interaction with blood, studied products alone and by combinations of studied products with blood versus contact time

(-) no change, (#) visual changes, (+) pitting corrosion

of the product was responsible for the observed pitting corrosion. However, the evaluation of this result should consider that the interaction between heparinised sheep blood with this type of test pieces showed no corrosion even when the concentration of chloride ions were ten times higher than in cleaner 2.

Based on the results of our investigation it can be expected that no corrosion will occur when applying the studied products on surgical instruments at contact times up to six hours. Cosmetic changes like brightening of bead blasted surfaces can not be excluded (Figure 2). Composition of foam sprays are crucial in respect



Fig. 2: Brightening and pitting corrosion on test piece made of stainless steel X20Cr13 with bead blasted surface after 72 h interaction with mixture from cleaner 2 and blood in ten-times magnification

Material		X46Cr13 brushed				X46Cr13 bead blasted				X46Cr13 grinded			
Contact time	Study product	C1	C2	C3	C4	C1	C2	C3	C4	C1	C2	C3	C4
06 h	Blood	-	-	-	-	-	-	-	-	-	-	-	-
24 h	Blood	-	-	-	-	-	-	-	-	-	-	-	-
72 h	Blood	-	-	-	-	-	-	-	-	-	-	-	-
06 h	Cleaner	-	-	-	-	-	#	-	-	-	-	-	-
24 h	Cleaner	-	-	-	-	-	#	-	-	-	+	-	-
72 h	Cleaner	-	-	-	-	-	#+	-	-	-	+	-	-
06 h	Cleaner + blood	-	-	-	-	-	#	-	-	-	-	-	-
24 h	Cleaner + blood	-	-	-	-	-	#+	-	-	-	+	-	-
72 h	Cleaner + blood	-	-	-	-	-	#+	-	-	-	+	-	-

Table 4: Surface changes on stainless steel X46Cr13 caused by interaction with blood, studied products alone and by combinations of studied products with blood versus contact time

(-) no change, (#) visual changes, (+) pitting corrosion

to their corrosion potential of instruments with grinded surfaces, such as hinges or cutting surfaces, when applying these products longer than six hours.

Corrosion or cosmetic changes are observed on anodized aluminium surfaces in alkaline or acidic environments. As expected all aluminium test pieces with

anodized surfaces are durable against all studied products due to the acceptable pH value of the mixtures.

The Working Group Instrument Preparation (AKI) recommends transport without application of cleaners or disinfectants from the point of use to the reprocessing area (dry transport) when the timeframe

is less than six hours after use. This recommendation is made in consideration of material protection and the cleaning ability of soiled instruments (3). Procedures for keeping the instruments moist are reasonable in situations where longer timeframes between use and reprocessing exist and if material damages/corrosion can be excluded. Our investigation shows for most of the studied products when used for one exposure period that this pre-condition is realized.

The cleaning ability of these types of products at longer storage time was not the objective of this study. Further studies should investigate the moisturizing and rinsing behaviours of foam cleaners at contact times longer than six hours, considering the described observations (Table 2). ❄

References

1. ANSI/AAMI ST79:2006: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
2. EN ISO 7153-1:2001-02: Surgical instruments - Metallic materials – Part 1: Stainless steel
3. Instrument Preparation Working Group. Proper maintenance of instruments 9th revised ed. Morfelden-Walldorf (Germany), 2009