Standardization of precleaning and automated reprocessing of robotic instruments

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Background:
Cleaning of complex robotic instruments in the way the manufacturer indicates, is significantly dependent on intensive manual precleaning. Subsequent reprocessing in a washer-disinfector appliance (WD) is only carried out to ensure a certain standardisation of residual contamination at a suitable low level. But the programme run times and the consumption of rescources are inappropriately large for just three or four robotic instruments per load in the WD.
For precleaning there is also now a treatment system, which treats the robotic instruments with a pre-set programme. It utilises not only ultrasound, but also rinses the interior in a standardised way. At the same time a reciprocator is used to move the Bowden cables via the control wheels of the instruments.

Material and Methods:
This system was tested according to the test protocol provided by the instrument manufacturer, to see what exactly this ultrasound appliance contribute to the required completed cleaning performance and what the subsequent cleaning in the WD then still has to achieve. The end result must be adequately cleaned instruments available for use.

Results:
On account of the protein and haemoglobin analytic performance results of the treatment system using ultrasound, the manual precleaning could be substituted and the WD process could be reduced in run time and resource consumption. This considerably reduced the burden on the processing unit for medical devices (CSSD).

Conclusion:
The establishment of this combination of ultrasound appliance and WD in a CSSD confirmed the high efficacy and fulfilment of the relevant requirements at the cleaning test of robotic instruments soiled by actual use. Unfortunately, however, this does not apply to all robotic instruments in the same way, because for cauterising instruments the treatment in an ultrasound appliance is not sufficiently effective. At the moment for these instruments the results still depend on careful manual cleaning, i.e. accurate brushing of the functional end.

KEY WORDS
- Robotic instruments
- ultrasound treatment
- washer-disinfector
- residual protein
- haemoglobin test
- cauterisation instruments

Introduction

Robotic surgical instruments are of a very complex design and make ultra stringent demands on cleaning. In no other country is cleaning of instruments soiled during everyday use verified so thoroughly through performance qualification and routine checks as in Germany. Thanks to that approach, it soon came to light that the increasing use of robotic instruments in hospitals was often accompanied by inadequate cleaning standards (1). That also meant that now the supervisory authorities began to pay closer attention to how these instruments were reprocessed, something that in turn led to more intensive testing of the cleaning processes as well as to very dubious investigations by laboratories, which were really not fit for that task (2). In recent years the manufacturer of robotic instruments has issued more detailed cleaning instructions, ranging from conditioning already in the operating room (OR) through manual precleaning steps to automated cleaning and thermal disinfection. The specific processes have been tested in accordance with the specifications and released by the manufacturer for (robotic) instrument reprocessing. Another important aspect was that personnel in the Reprocessing Units for Medical Devices (CSSD) were given additional training by the manufacturer, leading to significantly better residual protein test results, which in general are now no longer a cause for concern (3).
Manual precleaning of robotic instruments makes stringent demands on the CSSD personnel entrusted with that task and the associated time investment is considerable. The intricate working end of the instruments must be virtually completely clean before the instruments can undergo reprocessing in the washer-disinfector (WD). That appears advisable also in view of the fact that the WD does not activate or move the instrument joints, guide rollers or Bowden cables during the process, hence soils may be retained in many contact areas. While there is a seal between the functional end and the internal shaft area, its sealing function is limited. Movement of the Bowden cables, in particular, leads to the transfer of soils into the distal internal shaft area. Based on information

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from the manufacturer, in unfavourable cases this can be as high as 600 µl blood, as is simulated when testing the performance of WD processes: 600 µl reactivated heparinised sheep blood is injected via a thin tube advanced through the instrument irrigation tube as far as the seal. The instrument is then held obliquely by the distal end, around 15 ° above the level of the casing, and then rotated to somewhat distribute the blood. Whether that really simulates everyday practice appears questionable.

Precleaning prior to automated reprocessing also includes the critical internal shaft area, i.e. soaking and pressure cleaning with a pistol until no coloured fluid emerges any longer.

So what remains now for the automated process to accomplish? This has not been investigated using a differentiated approach. The processes employed in the recommended WDs have extensive cleaning steps using enzymatic, surfactant-based and mildly alkaline (pH ~10) detergents at temperatures in the range 45 to 55 °C for 20 to 30 minutes, which together generally produce reasonable results. It appears that the WD process only has to add the finishing touches, i.e. to standardize the residual protein load to an acceptably low level and pave the way for meticulous rinsing and finally for thermal disinfection. However, the cleaning outcome on the whole is determined by meticulous manual precleaning.

With the aim of enhancing standardization of manual precleaning, an ultrasonic bath was designed and fitted with a moving and a cleaning /irrigation device which provided for movement of the robotic instrument Bowden cables during sonication as well as for alternating suction and pressure cleaning of the irrigation channels. The purpose of this testing was to ascertain whether and to what extent this ultrasonic bath was able to take charge of the entire precleaning step and to determine what cleaning performance was still needed in the WD to assure an overall acceptable cleaning outcome. The next step was to investigate in the laboratory the combination of ultrasonic and irrigation-based precleaning as achieved with the ultrasonic bath and with an adapted WD process, and afterwards testing this combination in the field, using instruments with everyday soils.

Fig. 1: Functional ends of MCS I and MBF III

Materials and Methods

As process challenge devices (PCDs) two 8 mm Monopolar Curved Scissors (MCS) and two 8 mm Maryland Bipolar Forceps (MBF) of the new Xi generation from Intuitive Surgical Inc., Sunnyvale, CA USA (see Tab. 1) were used in each test run. In all test series one Monopolar Curved Scissors was run as a negative control.

Before beginning the tests, the instruments were first subjected to three complete cleaning and thermal disinfection processes (Vario TD) with neodisher Mediclean Forte (Dr. Weigert, Hamburg) as detergent, so as to remove any residues from the manufacturing process, storage or transport.

Heparinised sheep blood (ACILA Dr. Weidner GmbH, Weiterstadt) was used as test soil; this was diluted with 10% water to improve wetting and penetration into the intricate instrument structures. Protamine sulphate was added to activate sheep blood coagulation immediately before application of the test soil.

The test soil was applied to the instruments in accordance with the manufacturer's protocol.

A thin Teflon tube was introduced in a horizontal position via Port 1 and advanced as far as the internal distal end/seal of the shaft and then 600 µl of the reactivated blood was injected with a disposable syringe. In the case of the MCS instruments, the openings in the distal end of the shaft were sealed with Parafilm from the outside. To ensure the entire amount of blood was introduced, 1 ml air was next injected into the tube. The distal end was held upwards at an angle of around 15 ° and all control wheels on the casing were turned thrice in both directions.

The functional ends of the instruments (see Fig.1) were contaminated by immersing them in a test tube containing 5 ml reactivated blood, completely wetted and likewise all control wheels on the casing were turned thrice in both directions. The instruments were left in a horizontal position for 60 minutes at room temperature, after which they were processed in the ultrasonic bath.

To preclean the Xi instruments the ultrasonic bath TRISON 4000 (BANDELIN, Berlin) was fitted with the corresponding TWIST 4000 Xi-R device. Before each precleaning series, the bath was filled

Table 1: Test instruments

Instrument	Designation	LOT
MCS I	8 mm Monopolar Curved Scissors	N101601140 021
MCS II	8 mm Monopolar Curved Scissors	N101601140 005
MBF III	8 mm Maryland Bipolar Forceps	S101606200 023
MBF IV	8 mm Maryland Bipolar Forceps	S101606200 021
MCS V	8 mm Monopolar Curved Scissors	S131511120 066

with 42 litres demineralized water, 1% v/v detergent (MediClean forte, Dr. Weigert, Hamburg or thermoShield Xtreme, Dr. Schumacher, Malsfeld) was added and the degassing programme run. Next, the contaminated Xi instruments were connected to the TWIST device, the latter was lowered into the bath and the robotic instruments' programme started.

The first tests revealed that the ultrasonic bath's TWIST moving device was unable to move, or move to the required extent, the control wheels due to too high resistance. Therefore the moving device had to be reprogrammed to achieve almost double the control wheel torque normally needed for the Si instruments.

There was also a problem with a TWIST connector (plug) which meant that some instruments were not at all moved. The fault was signalled by Twist by means of a red light. Compared with our previous experiences with the Si instruments, the instruments made available for these experiments were very sluggish, no doubt due to the smaller control wheels and the 90 ° deflection of the Bowden cables in the casing; likewise, manual movement at the time of sample recovery proved difficult. Hence, an implement for manual movement was designed and used.

At the end of the programme, with confirmation by the control system that the process had met all criteria, including the measured flow rates, the instruments were removed one after the other and via Port 1 carefully rinsed thrice with 10 ml demineralized water. Likewise, using a laboratory spray bottle, the outside of the shaft and the functional end were rinsed with demineralized water for 10 seconds and then purged dry with compressed air on the inside and outside.

By rinsing it was thought that a large portion of the soils already dissolved in the cleaning solution will have been removed. The control wheels for moving the instruments were not moved at the time of rinsing. Hence, already dissolved soils will no doubt have been retained in certain areas. On the other hand, had these control wheels been moved this would have falsified the cleaning efficacy result. But the method used was intended to give an approximate idea of the cleaning action generated by the ultrasonic bath on its own.

After reprocessing the contaminated instruments, the uncontaminated instrument was reprocessed as a negative control in the same bath solution with the dissolved contamination in order to ascertain the nature of the contamination originating from the bath. On completion of the process this instrument was rinsed with demineralized water and purged dry with air on the inside and outside as described above.

Sample taking or sampling by elution of the instruments with, in each case, 6 ml 1% sodium dodecyl sulphate solution pH 11 was carried out exactly according to the type I test method published by the Da Vinci working group (4, 5).

The first experiments demonstrated that the detergent in itself was endowed with more or less pronounced OPA sensitivity due to its primary amine constituents, thus giving rise to interference with the OPA method. Since the eluates still contained detergent residues because of the limited results achieved on rinsing the instruments on the inside and outside, in the interest of obtaining objective results it was not deemed appropriate to apply the modified OPA method for eluate protein quantification. Therefore the Roti®-Quant universal (Article 0120.1, Carl Roth, Karlsruhe) modified BCA method with photometric measurement at 503 nm was used instead, yielding adequately high sensitivity and good linearity. Based on how the method was applied, the limit of quantification (LOQ) was around 3.5 µg protein (BSA) per ml eluate or 21 µg per instrument, i.e. for the 6 ml SDS solution used.

Furthermore, for orientational purposes this was followed by the Medi Test Combi V (Macherey & Nagel, Düren): semi-quantitative testing of each eluate solution for haemoglobin, using test sticks for detecting microhaematuria (6) .The colour comparison chart indicates haemoglobin as the number of erythrocytes (Ery) [red blood cells –RBCs] per µl, with a gradation scale of 10, 50 and 250 Ery/µl.

The UNICLEAN PL II (MMM, Planegg) was the washer-disinfector used in both the laboratory and the field for combined reprocessing of instruments in the ultrasonic bath followed by the WD process. The same detergent was used for the combination of ultrasonic bath and WD, at a concentration of 1% v/v in the ultrasonic bath and 0.6% v/v in the WD.

Results

Following test run 2, there was visual evidence of residual soils on the MBFs. On contaminating the MBFs through immersion in 5 ml blood, a thick coagulated blood droplet remained in the space between the cables and deflexion pulleys which doesn't really dry. This soft coagulum is thought to absorb the ultrasound energy like a "sponge" but is not fully dissolved by it. This is unlikely to happen under everyday use conditions and appears to be a specific problem related to the MBFs, and this small amount of residual soils would have been easily removed through a short rinse in the WD. This would not even have made any major demands on the WD cleaning performance. Therefore for the subsequent experiments, after applying the test soil, the size of the residual blood droplet was somewhat reduced by briefly tapping against the shaft.

The negative controls served to measure the contamination level deposited in the MCS from the ultrasonic bath and which was not removed due to the intentionally inadequate manual rinsing used before sample recovery. Most of the residual protein identified was easily removed by means of intensive rinsing and a small amount became lodged between the contact areas of wires, rollers, etc. Accordingly, from the ultrasonic bath cleaning performance results it would have been possible to subtract a considerable proportion of the residual protein on the negative controls. Because of the openings before the MCS distal internal seal, this instrument underwent more intensive rinsing and it is thought that the residual protein values obtained for the MBF as negative

Fig. 2: Visible blood residue on Maryland bipolar forceps of test run 2

control would have been higher and, as such, higher values could have been subtracted.

The tests which were carried out in accordance with the manufacturer's protocol demonstrated that the ultrasonic bath performance on its own was essentially able to meet the specifications stipulated for qualification as adequately cleaned instruments (see Tab. 2).

Therefore combined reprocessing in the ultrasonic bath and WD was investigated, while using a markedly shorter cleaning process for the WD. A pre-rinse step was omitted and the cleaning step shortened to 5 minutes at 55 °C using 0.6% detergent. The two intermediate rinse steps incorporated into the UNICLEAN PL robotic instruments' programme were retained. At the end of this process the instruments were purged with compressed air on the inside and outside, followed by sampling and determination of the residual protein amount (see Tab. 3).

Next, combined reprocessing of the robotic instruments after actual use was investigated in a CSSD (Caritas Krankenhaus St. Josef in Regensburg) in a similar way for initially five batches (see Tab. 4). Since a number of other instruments that needed no pretreatment were included additionally, the WD process was somewhat modified and the instruments reprocessed at 55 °C for 10 minutes using 0.6% detergent.

As in all previous tests, for the first batch the instruments were placed in the ultrasonic bath immediately after use without precleaning and the process was started. However, for the curved bipolar dissector it was noted that the working end was almost as soiled as before ultrasonic cleaning (see Fig.3). This instrument was then thoroughly recleaned with a brush and placed in the WD with the other instruments. The cleaning results obtained for the cauterization instrument were borderline and hence not satisfactory. For the second batch after precleaning for 5 minutes with the instruments' programme in the ultrasonic bath, the cauterization instrument was withdrawn and the working end cleaned with a brush. Cleaning was not as thorough as when using manual reprocessing alone, since the robotic instruments' programme of the WD followed. After reprocessing in the ultrasonic bath followed by the WD process, haemoglobin and protein values

Table 2: Residual protein and haemoglobin results after precleaning in the ultrasonic bath – test runs 1 to 5

Instrument	Optical	µg protein per instrument	Haemoglobin ery per µl eluate
Test run 1			
MCS I	Negative	55.5	0
MCS II	Negative	<LOQ	0
MBF III	Negative	41.8	10
MBF IV	Negative	34.9	0
MCS V as negative control	Negative	34.9	0
Test run 2			
MCS II	Negative	90.3	0
MCS V	Negative	76.5	0
MBF III	Red residue in the functional end space	296.6	50
MBF IV	Red residue in the functional end space	344.6	50
MCS I as negative control	Negative	42.1	0
Test run 3			
MCS II	Negative	48.6	0
MCS V	Negative	76.2	0
MBF III	Negative	96.8	10
MBF IV	Negative	131.2	10
MCS I as negative control	Negative	55.5	0
Test run 4			
MCS II	Negative	<LOQ	0
MCS V	Negative	124.3	50
MBF III	Negative	<LOQ	10
MBF IV	Negative	138.1	50
MCS I as negative control	Negative	21.2	0
Test run 5			
MCS II	Negative	55.5	0
MCS V	Negative	117.4	50
MBF III	Negative	41.8	0
MBF IV	Negative	165.0	10
MCS I as negative control	Negative	28.0	0

<LOQ = less than the limit of quantification

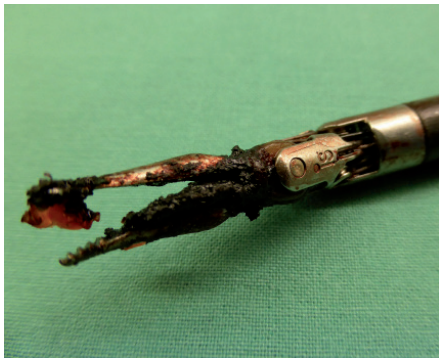

Fig. 3: Cauterization residues on functional end of curved bipolar dissector

on an unacceptable scale were identified. Ultrasonic treatment had practically no cleaning effect in terms of the residual protein amount on the cauterization instruments and their working ends still needed thorough manual precleaning.

For the further instrument reprocessing batches the cauterization instrument was always precleaned for 5 minutes in the ultrasonic bath to facilitate cleaning with a brush; it was then carefully cleaned with a brush while moving the functional end by means of the control wheels and then inspected with a magnifying lamp for cleanliness. Only then was the instrument placed with the other instruments in the ultrasonic bath, followed by cleaning in the WD. That approach produced much better results. Nonetheless, major fluctuations were noted in the quality of the results obtained for the cauterization instruments, as seen in the case of the batch 5 results, which, however, were perfectly acceptable.

A few weeks after investigation of the five reprocessing batches, testing was carried out once again for two batches in the CSSD (see Tab. 5)

For this second batch the instruments were delivered from the OR only in the evening shortly before the end of the working day. That meant that manual brushing was done in haste and not so thoroughly, which explained the high residual contamination level on the curved bipolar dissector. That clearly demonstrates the relationship between manual precleaning steps and staff-related factors.

Table 3: Residual protein and haemoglobin results after combined cleaning in the ultrasonic bath and WD

Instrument	Optical	µg Protein per instrument	Haemoglobin ery per µl eluate
Test run 1			
MCS I	Negative	<LOQ	0
MCS II	Negative	<LOQ	0
MBF III	Negative	<LOQ	0
MBF IV	Negative	<LOQ	0
Test run 2			
MCS I	Negative	<LOQ	0
MCS II	Negative	28.04	0
MBF III	Negative	<LOQ	0
MBF IV	Negative	<LOQ	0
Test run 3			
MCS I	Negative	<LOQ	0
MCS II	Negative	<LOQ	0
MBF III	Negative	<LOQ	0
MBF IV	Negative	<LOQ	0
Test run 4			
MCS II	Negative	<LOQ	0
MCS V	Negative	21.2	0
MBF III	Negative	41.8	0
MBF IV	Negative	21.2	0

*** After precleaning in the ultrasonic bath a red "fibrin sponge" was still visible in the guide roller space in MBF VII. Otherwise all instruments were optically clean after precleaning.**

<LOQ = less than the limit of quantification

Table 4: Results after reprocessing robotic instruments, harbouring everyday soils, with the combined processes in a RUMED

Batch	Instrument	Haemoglobin ery per µl eluate	µg protein per instrument
1	Curved Bipolar Dissector	10	98.1
1	Monopolar Curved Scissors	0	<LOQ
1	Large Needle Holder	0	<LOQ
2	Large Needle Holder	0	<LOQ
2	Monopolar Curved Scissors	10	<LOQ
2	Curved Bipolar Dissector	10–50	144.2
3	Large Needle Holder	0	23.4
3	Monopolar Curved Scissors	0	<LOQ
3	Curved Bipolar Dissector	0	23.5
4	Monopolar Curved Scissors	0	<LOQ
4	Large Needle Holder	0	<LOQ
4	Curved Bipolar Dissector	0	<LOQ
5	Large Needle Holder	0	23.4
5	Monopolar Curved Scissors	0	23.4
5	Curved Bipolar Dissector	10	75.0

<LOQ = less than the limit of quantification

Discussion

According to the ultrasonic bath manufacturer, the declared use of the ultrasonic bath is for precleaning or for use as a substitute for manual precleaning of robotic instruments as stipulated by the robotic instruments' manufacturer, following which the instruments should be finally cleaned, rinsed and thermally disinfected using the robotic instruments' WD process. These findings demonstrate that, thanks to its moving and cleaning/irrigation device, the ultrasonic bath on its own is not only able to preclean but also to take charge of the complete cleaning of robotic instruments. That means the WD now need only perform standardized rinsing and thermal disinfection.

The cleaning performance of the WD processes has been tested according to the same test protocol as that used by the instrument manufacturer; that protocol was also used to test the ultrasonic bath and essentially yielded results < 100 µg residual protein per instrument. These results demonstrate that after cleaning in this ultrasonic bath there is no need to call upon the full performance capabilities of the WD processes and that in the interest of cutting back on resources a much more restricted process suffices.

Manual precleaning of three instruments prior to the WD process takes around 30 minutes and the process in the ultrasonic bath needs about the same time. The time needed to reprocess robotic instruments in the WDs of different manufacturers is between 80 and 100 minutes. When (pre-) cleaning instruments in the test ultrasonic bath was combined with WD reprocessing, it was possible to reduce the WD processing time to 60 minutes. This enables CSSDs to free up capacity, especially in view of the fact that the WDs with only a few robotic instruments are almost empty and hence water and energy consumption is disproportionate.

The combination of cleaning as assured by the ultrasonic bath and shortened WD process can be deemed to be very effective. Using a standardized method devised by the Da Vinci Working Group, this combined cleaning process is able to reduce the residual protein amount on shaft instruments, such as needle holders and scissors, to well below 50 µg per instrument. Hence, there is often the aspiration to obtain such results for other, less intricate instruments, too.

Table 5: Results after retesting two batches after a few weeks

Batch	Instrument	Haemoglobin ery per µl eluate	µg protein per instrument
1	Curved Bipolar Dissector	10	77.2
1	Large Needle Driver	0	<LOQ
1	Monopolar Curved Scissors	0	47.9
2	Curved Bipolar Dissector	50	113.8
2	Large Needle Driver	0	<LOQ
2	Monopolar Curved Scissors	0	25.9

<LOQ = less than the limit of quantification

It is indeed surprising that there are publications that report finding residual protein amounts in the milligram range after manual and automated reprocessing of robotic instruments (7, 8). Unfortunately, it is not at all easy to understand the methodological and analytical background to these reports. Either the manufacturer's reprocessing instructions were not observed or interference factors had impacted the analytical method used and, accordingly, the findings. For example in the case of sampling underpinned by ultrasound, tungsten particles can go into solution and, with the applied BCA method, reduce the copper (II) of the reagent (electromotive series of metals), which is then incorrectly signalled as additional protein.

The distal internal area before the seal with the fed through Bowden cables leading to the functional end, which is deemed critical with regard to cleaning, is apparently and effectively also cleaned in the ultrasonic bath thanks to the additional movement of the Bowden cables as well as the suction and pressure cleaning. Using a strip of aluminium foil that was inserted into this shaft area after disconnection of the distal functional end and then reconnected it was noted that ultrasound is effective in this area. Conversely, WD processes use only pressure cleaning, hence stagnation of the cleaning solution is always found before the internal distal seal regardless of the pressure level. That was demonstrated by flow simulation tests undertaken by the Lower Rhine Polytechnical College (9).

Cauterization instruments are an exception in that after use they harbour large quantities of thermally denatured proteins. Since these soils are of a rubber-like nature ultrasound treatment has virtually no effect. Immersion in a 3% hydrogen peroxide solution is often recommended for precleaning to facilitate manual cleaning of contaminated cauterization instruments (10). Our own experiments did not demonstrate any appreciable beneficial effect on using that method. Besides, based on the manufacturer's instructions hydrogen peroxide solution should not be used for treatment of robotic instruments since the Bowden cable wires are made of tungsten and are thus not resistant to that solution. As such, thorough cleaning with a brush, which is somewhat facilitated by ultrasonic pretreatment, must for the time being continue to be the cleaning method of choice for the working end of cauterization instruments. Special attention should be paid to cleaning these instruments at the time of performance qualification and during routine tests and the cleaning outcome should be routinely verified for these instruments. For this purpose, using SDS solution and a vortex mixer (Vortexer), the instrument functional ends should be extracted and the extract tested by means of microhaematuria test strips for haemoglobin (≤ 10 Ery/µl) (6). There are also test systems where the distal end of the instruments is inserted through a septum into a vessel with a reagent solution. The reagent solution with Coomassie Brilliant Blue takes on a more or less intensive blue colour in accordance with the protein amount under phosphoric acid conditions (Bradford

method) (11). That method will not work with regard to adherent, denatured proteins since the phosphoric acid environment tends to have an additional protein fixing effect and, to generate a colour reaction at all, the protein must first of all pass into solution.

In conclusion, it must be noted that the cleaning methods available for cauterization instruments are unsatisfactory and that at present the cleaning results are dependent alone on manual cleaning with a brush. Innovative developments are needed here to overcome that dependency. ■

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