Original Article

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Conflict of interest:

All authors confirm that there is no conflict of interest according to the guidelines of the International Committee of Medical Journal editors (ICMJE).

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Summary

Instruments baskets made from sheet metal (compared to wires) protect instruments better but drying and cleaning performance are frequently controversially discussed. This study compares drying of loads of 50 standard instruments in wire and sheet metals baskets under different drying temperatures and times, with and without rinse aid (different formulas and dosages). The weight difference is measured before and after cleaning in repeated cycles.

Keywords

- surgical instrument
- decontamination
- instrument baskets
- cleaning
- drying

The cleaning performance is compared by a PCD (Process Challenge Device) system (Helimatic Performance Qualification), which is based on a detachable box-locks und two different cleaning processes.

It turns out that for both parameters there is no significant difference of the results by the basket design.

The drying result is mainly influenced by the drying time and the position in the chamber (the drying temperature is less influential). The use of rinse aid can shorten the drying time under these circumstances by 5-10 min. The cleaning performance was in similar ways influenced by process design and level in the chamber.

Another common observation in daily practice are stains on instruments which mirror the basket structure, either after cleaning/disinfection or steam sterilization. This has to be addressed by optimizing the media quality. So processes should be optimized based on worst case positions and loads based on the individual installation and process requirements.

Background

There are different designs of instrument baskets in the market, based either on wire mesh or on sheet metal grids (see Figure 1). While it is undisputed that sheet-metal-baskets provide a better protection of the content (penetration of instruments etc.), there are often concerns regarding cleaning and drying performance. However there is so far no evidence available actually comparing the performance of the various designs. The German society for Sterile Supply (DGSV) has published an advisory note in Central Service, but here potential advantages and disadvantages are only listed and not quantified nor tested . At the same time there is no precise information available about the effects of a rinse aid for a metal load.

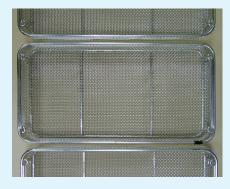


Figure 1 A: Wire Basket used for tests (mesh width 5 mm, 0,5 mm wire diameter)

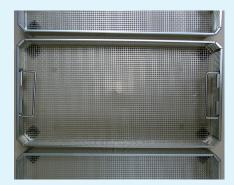


Figure 1 B: Mesh Basket (mesh width 4 mm, 1 mm bar)





Figure 2 A: Tray with instruments for drying

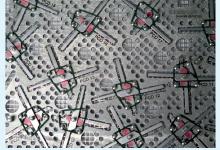


Figure 2 B: Sheet metal in basket (Level 2) to create spray shadows (without PCDs)



Figure 2 C: Load for drying tests

Goal

This article aims to test the cleaning and drying of instruments in the different basket designs with various process parameters under standardized conditions and to quantify potential differences also in terms of necessary process settings to achieve good results.

Material and Method

Baskets uses were commonly used designs with 480×240mm size, both made by Aesculap, Tuttlingen / Germany, according to Figure 1.

The investigation is split into drying and cleaning. For drying tests baskets are filled with sets of 50 standard instruments each. The sets were

Table 1: Settings of Drving Tests



Figure 2 D: Position of logger in Level 2

loaded according to the requirements of the "Red Brochure" [2], so all joint instruments are opened to 90° and evenly distributed in horizontal layers in the basket. The weight of each basket was $3 \text{ kg} \pm 300 \text{ g}$. One wire basket and one sheet metal basket were loaded side by side on the levels 1, 3 and 4 of the washer disinfector. Level 2 was filled with a sheet metal template (see Figure 2 A–C).

The test are performed in a Washer Disinfector Belimed WD290 (electrically heated). In order to simulate the different drying temperatures of various machines, drying temperature settings of 90°C and 110°C were used, which related to chamber temperature of about 40°C to 70°C (measured by Thermo-Logger EBRO EBI 10 TP231 in the geometric middle of the chamber, see Figure 2 D). The logger probe was mounted horizontally to avoid drips resting on the tip. Most washer disinfectors only indicate the temperature of the air entering into the chamber, but the temperature decreases significantly inside the chamber due to the evaporation of moisture. The temperature and drying performance is also influenced by the exhaust from the chamber, so that even machines of the same technical condition may have different results depending on installation.

In addition two different rinse aids were used (high and low tenside concentration) with two different temperature/time settings and at the high and low end of the manufacturers recommendation of dosage. Each test was repeated three times.

The sets are dried before the test in a heating chamber (55°C, 1h) and weighed before and after each test. The test cycle consists of two rinse cycles (1 min, cold demineralized water), a thermal disinfection 90°C with A_0 3000 and the drying process. After the cycle the baskets are cautiously removed from the machine and weighed immediately in plastic bins, in order not to loose any residual water.

The weight difference is an indicator of the drying performance. There is no exact definition for "dry" but in sets with a weight difference below ca 0.5 g no water could be detected visually or by feeling. A total of 51 runs is performed. Per run three results are produced for wire baskets and 3 results for sheet metal baskets (3 levels each). Comparison is done by absolute values and influence analysis. If not dried at all each tray has a weight gain of 20g-30g.

Time	Temp.	No rinse aid	Low Tenside 0.5ml/l	Low Tenside 2ml/l	High Tenside 0.5ml/l	High Tenside 2ml/l
10 min	110°C	1 a-c	7 a-c	11 a-b	9 a-c	13 a-c
15 min	90°C	5 a-c	8 a-c	12 a-c	10 a-c	14 a-c
	110°C	2 a-c				
20 min	90°C	6 a-c				
	110°C	3 a-c				
25 min	110°C	4 a-c				



Figure 3 A: Process Challenge Device

For cleaning performance a test model based on detachable Process Challenge Devices (PCDs) is used. They are contaminated by 100μ l each with Browne Test Soil and dried at 55°C for 1h.



Figure 3 B: PCDs in special trays (see also Figure 2B)

Twenty PCDs each are placed in special templates and after cleaning the area of residual red color is quantified by a camera system in mm² (Helimatic Performance Qualification (HPQ)).



Figure 3 C: Camera system

In the range of low to medium residual contaminations this value is roughly proportional to the protein residue on these PCDs [3].

Table 2: Processes for cleaning tests						
	Resource optimized process	Result optimized process				
Pre cleaning (no detergent)	1 × 2min	2 × 5min				
Cleaner Helimatic MA Dosage	5 ml/l	10 ml/l				
Holding time at 55°C	5 min	10 min				
Pressure during holding (driven by water level)	180 mbar	242 mbar				

Table 3: Results of Drying Test (average and minimum / maximum residual moisture of three trays in three runs)by Drying Temperature, Time and Rinse Aid

Drying time	Temp.	Rinse aid	Sheet Average/g	Min-Max/g	Wire Average/g	Min-Max/g
10 min	110°C	-	4.3	2/5	3.81	2 / 5.5
		Low/0.5	0.61	0/1.5	0.66	0/2
		High/0.5	0.39	0/1.5	0.33	0/1
		Low/2.0	2.2	0 / 6.5	3.7	0 / 4
		High/2.0	0.0	0/0	0.0	0/0
15 min	90°C	-	1.17	0.5 / 2	1.39	0 / 2.5
		Low/0.5	0.17	0 / 0.5	0.11	0 / 0.5
		High/0.5	0.0	0/0	0.1	0 / 0.5
		Low/2.0	0.0	0/0	0.0	0/0
		High/2.0	0.0	0/0	0.17	0/0
	110°C	-	0.17	0 / 0.5	0.28	0/1
20 min	90°C	-	0.11	0 / 0.5	0.28	0/1
	110°C	-	0.0	0/0	0.0	0/0
25 min	110°C	-	0.0	0/0	0.0	0/0



Again the washer-disinfector WD290 is loaded with three baskets in sheet metal and three basket in wire mesh design. Two different processes were used with two replications each, which represent a high and low end of hospital used cleaning processes [3].

The results of the cleaning tests are compared by average per tray (20 PCD each) but also by the maximum (worst three results) and the number of PCDs below 1.5 mm^2 (roughly equivalent to $100 \mu g$ of protein). Per run a total of 60 results are produced for wire baskets and 60 results for sheet metal baskets.

Results

The results in the drying process show, that the chamber temperature under all parameters first drops sharply due to the energy needed for evaporation of the water on the sensor (The starting temperature is always 90°C due to the temperature of the thermal disinfection). The lowest temperature ranges between 39°C and 60°C and seems only be higher with high dosage amount of rinse aid (due to less water at the sensor). After a time between 72s and 312s (which seems completely random) the temperature indicated starts to rise. The maximum temperature in the chamber (towards the end of the drying cycle) is driven by drying time, temperature and rinse aid and ranges from 41°C to 70°C.

For results with high amounts of moisture the temperature drops low over a longer period of time, but variances were large. Even with identical load and process parameters this temperature curve (and the drying results) differed, so part of this process (like location of water drops) seems also to be random driven (mathematic process explanation w/o rinse aid is 75% in a linear model). The temperature curve in terms of low and high temperature is by far more influenced by the drying time then by the set temperature. In the examples of Diagram 1 the blue and red curve show settings with 110°C, yellow and grey 90°C, the black line indicates a curve with high rinse aid setting (same machine setting as grey). It shows that by less water adhering to the products the temperature does not decrease so deep.

Looking at the results without use of rinse aid (Table 3), it turns out that the

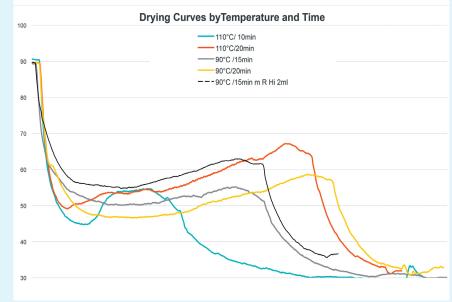




Table 4: Influence factors on drying in linear model							
Factor	Influence factor	p value	Comment				
Without rinse aid	Without rinse aid						
Basket	-0.016	0.774	Wire basket slightly better				
Level	0.498	0.000	Better result on lower level				
Temperature	0.312	0.000					
Time	4.150	0.000					
With rinse aid							
Basket	-0.047	0.508	Wire basket slightly better				
Temp. / Time	-0.356	0.000	Longer time (lower temp.) better				
Type rinse aid	-0.215	0.003					
Dosage	-0.103	0.149					

minimum time to get dry loads safely is 15-20 min, with rinse aid similar results can be achieved with 10-15 min (depending on temperature).

Analyzing influence factors in a linear model, it turns out that the drying time is by far the strongest factor, followed by the level of the tray (hot air is injected from the bottom of the machine). With rinse aid the type of rinse aid is more influential than the dosage. Higher dosages did not necessarily produce better results. Under both circumstances the influence of the tray design is by far the lowest influence and not significant.

Regarding the cleaning results there is (as expected) a higher amount of residue and a much higher variance with the resource optimized process (named as "low" in Diagram 2). Values fluctuate depending on level (level 3 (middle) normally being the worst) and position in the chamber (worst results typically in the corners).

The position influence is eliminated by comparing the results of the average and average of the worst three values

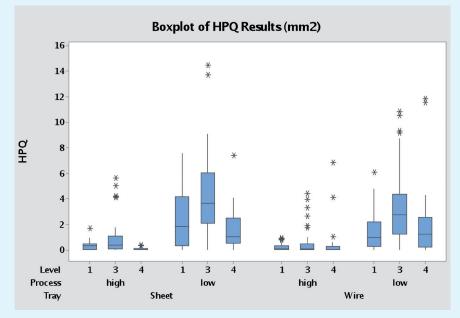


Diagram 2: Overview cleaning results by Basket type, Process (high, low) and Level

per level. Even on this basis the process explanation in a linear model is limited to 53% for the average and 75% for the maximum. The influence of process and level is significant.

Looking at the result optimized process (compared to resource optimized) the average residue drops from 2.54 mm² residue to 0.42 mm². The maximum (as calculated above) even drops from 6.48 mm² to 1.84 mm² (average of all basket types). Looking at the comparison between the different processes and tray designs (Table 5), it seems that for both (average and maximum), there is no significant difference between the trays (p=0.47/p=0.67) and the influence factor in a linear model is low. It can be noted that the influence factor of the level is higher than the process influence.

Conclusion

The results show that differences between wire baskets and sheet metal baskets in terms of drying performance and cleaning results are not significant and small. So there is no objection against the use of sheet metal baskets for better instrument protection. The test results only apply to the designs tested in this study, other geometries may react different.

Drying performance is mainly influenced by the drying time used and less by the temperature. Temperature in the chamber stays way below the temperature of the incoming air. The cleaning performance is strongly driven by the process and the position but shows a strong variance. In both tests the position in the chamber has a large influence on the result. The drying of the used load of metal instruments can be shortened by 5 to 10 min by the use of a rinse aid. A high concentration of tensides is beneficial while the dosage has low influence.

The data created is limited in terms of quantity of values and chosen process parameters, however the data shows that the idea of an inferior performance of sheet metal baskets in terms of cleaning and drying can not be supported.

Discussion and Consequences for daily Operation

Based on the results it can not be expected that a change of the basket design (between the tested designs) improves or decreases cleaning results or drying performance in a noticeable way. The experiments show multiple influence factors which make clear observation without laboratory studies difficult.

Another common observation in daily practice are stains on instruments which mirror the basket structure, either after cleaning/disinfection or steam sterilization. This is however driven by poor media quality and such water evaporating from the contact points between instrument and basket. This has to be addressed by optimizing the media quality.

Regarding drying it has to be noted that all Washer -Disinfectors known to the authors use a drying temperature as the temperature of the air going into the chamber. This setting alone only gives a very limited indication of the real drying performance of a machine. The drying is further influenced by

Table 5: Comparison of cleaning results and influence factors on average and maximum per tray						
	Sheet metal / mm ²	Wire / mm ²	p value / Factor Tray	p value / Factor Process	p value / Factor Level	
Average						
Resource optimized (low)	2.73	2.29	p=0.470	p=0.000	p=0.009	
Result optimized (high)	0.46	0.38	0.134	-1.043	1.386	
Maximum						
Resource optimized (low)	6.35	6.61	p=0.669	p=0.000	p=0.000	
Result optimized (high)	1.72	1.96	-0.125	-2.320	4.109	



- the temperature reached in the chamber
- the air flow achieved
- the humidity level in the chamber
- the airflow inside the chamber

These factors not only differ by machine design but also by the individual installation (exhaust air etc.), so the settings used here to achieve dry sets can not be transferred one to one to other machines and installations. Drying performance will also largely depend on the load in terms of total weight and material (especially plastics are much harder to dry than metal).

It is not realistic in clinical settings to load a machine according to the drying performance, so the variance between the levels has to be dealt with by worst case scenarios. To achieve a constant satisfactory drying result the following steps can be recommended:

- Check the airflow, moisture and temperature situation of the specific machine and installation, Temperature can be set to the possible maximum.
- Define an acceptable drying level (many facilities tolerate small amounts of water directly after the cycle)

- Check worst case load and define the drying time required
- The drying time may be reduced about 5–10 min with the use of rinse aids. Questions of potential stain and material compatibility have to be addressed.

For cleaning the test system shows a strong influence of position and level, which can not be accommodated when loading the machine. So the process also has to be also based on the worst position. For a stable processes

- Process performance has to be evaluated. There is no international consensus yet, how this shall be performed, but the system HPQ has shown that in can detect a large variety of influence factors quickly and precisely [3].
- Depending on results, the process may have to be optimize. The influence of various parameters has been researched [3] but results have to be verified for the individual process.
- Due to the non-controllable factors (condition of the devices upon arrival, position in the machine) a safety factor should be included and process settings and times should be chosen generously.

This study shows, how with limited efforts evidence and a basis for decisions can be created. Even long term existing statements regarding reprocessing should be checked whether they can be backed up by experiments and evidence.

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