Surgical Reprocessing Washer Disinfector Trials Comparing Non-enzymatic, Enzymatic, and Alkaline Detergents Using Industry Recognized Test Soils

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Abstract

Proper cleaning of reusable medical instruments prior to disinfection or sterilization is critical in eliminating the potential for cross-contamination among patients. A wash study was conducted by WFK Testgewebe in Brüggen Germany comparing medical device cleaning detergents using standard operating procedures. WFK used a Miele PG 8535 washer-disinfector (WD) to compare cleaning of industry recognized indicator/verification soils as well as manually soiled Crile-scissors. Treatments included a water only cycle to observe the effects of temperature and mechanical action, an alkaline detergent, a non-enzymatic detergent and two enzymatic detergents each with a different protease. Each treatment was run twice using a forty minute wash cycle. The commercial indicators were evaluated visually and demonstrated that temperature and mechanical action alone were not enough to clean the indicators. The enzymatic detergents were by far the best performing treatments and were able to remove substantially more soil from the indictors as compared to the detergent base (without enzymes) and the alkaline detergent. The manually soiled Crile-scissors were evaluated using a quantifiable residual protein detection method. The results indicated inconsistencies in the soiling method and were inconclusive.

Background

An estimated 312.9 million surgical procedures were performed in 2012, an increase of nearly 34% over an eight year period [1]. This number will continue to climb as the global population increases and access to medical care becomes more wide spread. As the number of surgeries increase, so will the use of reusable medical devices and instruments. Additionally, with advancements in medical equipment come more delicate and complex designs that can be difficult to clean. During surgical procedures, reusable medical devices and instruments become soiled and contaminated with blood, tissue and other biological materials that need to be removed.

Thorough cleaning of contaminated devices and instruments is essential prior to high-level disinfection or sterilization, and failure to adequately clean can interfere with subsequent reprocessing [2]. Improperly cleaned devices and instruments can leave behind residual organic soil that can inactivate disinfectants and protect microorganisms during the disinfection process [3]. The potential transfer of microorganisms from poorly cleaned medical devices increases the risk of a serious healthcare acquired infection (HAI). Unfortunately, the number of HAIs attributed to improperly processed devices is unknown as it is not often investigated as a cause of infection [4]. While HAIs associated with reusable devices is not well studied, it is not a new phenomenon. Recent news and journal articles have highlighted a link between the two [5][6].

Cleaning of reusable medical devices can be performed manually or mechanically. The devices can be physically scrubbed by hand or flushed with high pressure fluids to reach crevices that cannot be reached with manual scrubbing. In other cases, facilities may have automated systems such as ultrasonic cleaners and washer-disinfectors at their disposal [2]. The automated systems may also be specific to the types of instruments and devices that a facility reprocesses. Regardless of the means by which a facility reprocesses reusable instruments, adequate cleaning requires the use of detergents. In many cases, the detergent of choice contains enzymes such as proteases to enhance cleaning by breaking down proteinaceous soils which comprise a large portion of medical soils. Enzymatic detergents may also contain lipases to enhance the removal of fatty soils, and carbohydrases to enhance the removal of soils associated with mucous membranes and fecal matter. Alkaline (high pH) detergents are also used for reprocessing. Unlike enzymatic solutions, alkaline detergents use harsh

chemicals to dissolve organic soils associated with dirty medical devices and instruments. This study was launched to compare the cleaning ability of non-enzymatic detergents, enzymatic detergents and alkaline detergents at an independent testing facility in Germany. A wash without any detergent was also performed as a control, to study the effects of temperature and mechanical action alone.

Materials & Methods

Test Facility

WFK Testgewebe GmbH in Brüggen, Germany was chosen as the test facility as they specialize in application based testing and use machinery commonly employed in medical device reprocessing. Samples of a detergent with and without enzymes, and an alkaline detergent were sent to WFK.

Test Soils

Obtaining soiled devices from hospitals and clinics is neither practical nor feasible. Commercially available soiled indicator/verification strips and manually soiled Crile-scissors were used to demonstrate efficacy in a Miele PG 8535 washer-disinfector (WD). In this study, TOSI®, TOSI® FlexiCheck, Browne STF load checks and Simicon RI indicators (Table I) were chosen since they are well-known within the industry.

Table I. Indicator Soils

Manufacturer	Soil	Associated Containment Device
TOSI®	Blood components	Plastic holder that mimics tight spaces and joints
TOSI® FlexiCheck	Blood components and polysaccharide	Tubing that contains the flexi check and acts as a lumen/joints
Browne STF Load Check	Artificial soil with a dye indicator	Metal holder with grids to mimic tight joints and recesses
SIMICON RI	Blood components	Small plastic or metal box with holes to mimic soil trapped inside of a device

Each indicator was used in conjunction with its associated containment device. The containment devices are designed to make soil removal more challenging by mimicking the intricate joints, channels and recesses of common devices. TOSI® indicators contain a plastic cover that is tapered over the surface to mimic tight spaces and joints while the TOSI® FlexiCheck is sealed inside of flexible tubing to mimic devices with lumens or channels. STF Load Checks are clamped inside a metal holder with a gridded surface and SIMICON RI strips are placed inside a metal or plastic box containing holes to allow entry of cleaning agents. In addition to the commercial indicators, seventy manually soiled Crile-scissors were also prepared for testing. Thirty-five of the scissors were manually contaminated with a commercially available test soil, while the other thirty-five were manually contaminated with defibrinated sheep's blood.

Wash Procedure & Evaluation

The commercial indicators and the scissors were cleaned with five separate treatments (Table II). Each treatment was tested in duplicate with the same number of indicators (24 total indicators cleaned per treatment; 10 total manually soiled scissors). For each treatment and the first wash cycle, the indicators and their associated containment device were loaded into a Miele PG 8535 WD in triplicate along with three of the Crile-scissors soiled with the commercial soil, and two soiled with sheep's blood (Figure 1 & 2). In the second wash cycle, the WD was loaded the same as the first wash cycle, except in this wash cycle only two scissors soiled with the commercial soil were treated along with three soiled with sheep's blood. The Crile-scissors left out of the WD wash cycles were used as positive controls for subsequent residual soil analysis.

The wash cycle was approximately forty minutes long and included both a pre-cleaning rinse and a post cleaning rinse step. The actual cleaning segment of the wash cycle lasted five minutes and was held at a temperature of 40°C. After the run was complete, the commercial indicators were removed from their containment device, air-dried and visually evaluated for residual soil according to protocol. Any residual organic material on the Crile-scissors was eluted from the surface and quantified using the well-known bicinchoninic acid (BCA) protein detection assay. The reagents in the kit react with proteins forming a purple color that can be measured on a spectrophotometer at A562.

Table II: Treatments & Dose

Treatment	Dose (manufacturer's instructions)
Water Wash (no Detergent)	N/A
Alkaline Detergent	0.3%
Detergent* w/o enzyme	0.5%
Detergent* + 5% Liquanase Everis 900 L**	0.5%
Detergent* + 5% Savinase Everis 900 L**	0.5%

*same detergent; **Manufactured by Novozymes A/S

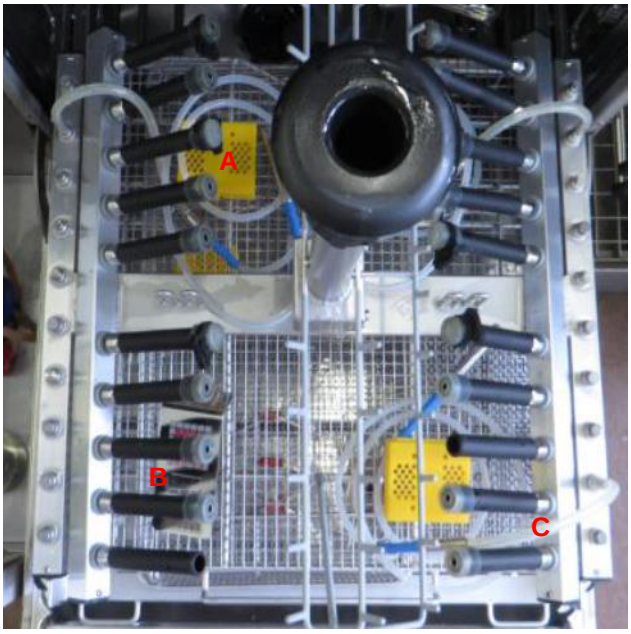

Figure 1: Image of WD rack with indicators in their associated containment device
(A) Yellow plastic case with holes containing SIMICON RI;
(B) Metal clamp with STF Load Check;
(C) Tubing containing TOSI® FlexiCheck. TOSI® not visible

Figure 2: Image of WD rack with indicators in their associated containment device and the Crile scissors.
(A) Yellow plastic case with holes containing SIMICON RI;
(B) Metal clamp with STF Load Check;
(C) Tubing containing TOSI® FlexiCheck;
(D) TOSI® contained in a metal tray;
(E) Crile-Scissors

Results

Commercial Indicator Results

After each indicator strip was removed from the WD and allowed to dry, it was ranked by WFK from 0-4 with a rank of zero being completely clean and a rank of four being an unwashed indicator. An average ranking was calculated for each indicator type. The data was then used to calculate a relative percent clean index. These average ranks were graphed (Figure 3) as a bar chart to demonstrate a cumulative relative percent clean index for each treatment. A cumulative rank of 400 would correspond to all 24 indicators from duplicate wash cycles being ranked with a zero (100% clean with no visible residue) while a cumulative rank of zero would indicate that all of the indicators were ranked with a four 0% clean). On a cumulative ranked basis the water wash (without detergent) had a relative index of about 53% while the commercial alkaline detergent and the commercial detergent without enzyme indexed at 86% and 84%, respectively. The commercial detergent with the addition of proteases indexed at 97% (w/ Liquanase® Everis 900 L) and 97% (w/ Savinase® Everis 900 L). Figure 4 provides a scale to better demonstrate the correlation between average rank scale and % clean.

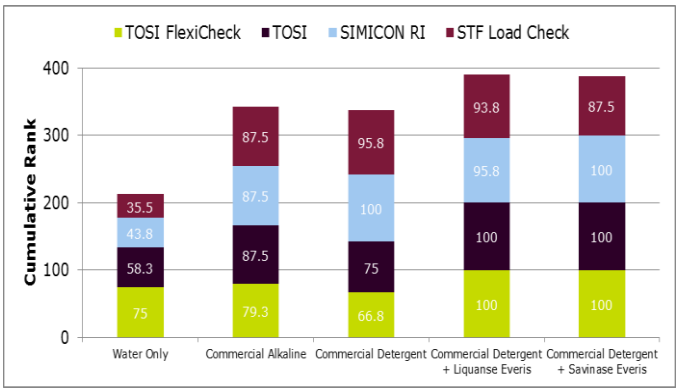

Figure 3: Cumulative Rank Index per Treatment (Individual ranks for each indicator shown by the white numbers with in each stacked block)

Average Rank Scale	% Clean
0.0	100
0.5	87.5
1.0	75
1.5	62.5
2.0	50
2.5	37.5
3.0	25
3.5	12.5
4.0	0

Commercial Detergent with Everis

Commercial Detergent & Alkaline Detergent

Water Only

Figure 4: Average rank index used by WFK

The data was also evaluated purely on the number of commercial indicators that were ranked with a zero (meaning that all or most of the soil was removed) versus anything above a zero (Figure 5). In other words, how many of the 24 total indicators washed were free of any residual residue. Viewing the data in this manner also demonstrates the differences between the treatments. The water wash alone was unable to completely clean any of the indicators, while the commercial detergent without enzyme and the commercial alkaline detergent cleaned less than 50% of all the indicators. The commercial detergent with a protease enzyme, cleaned over 90% of all the indicators in a five minute wash cycle.

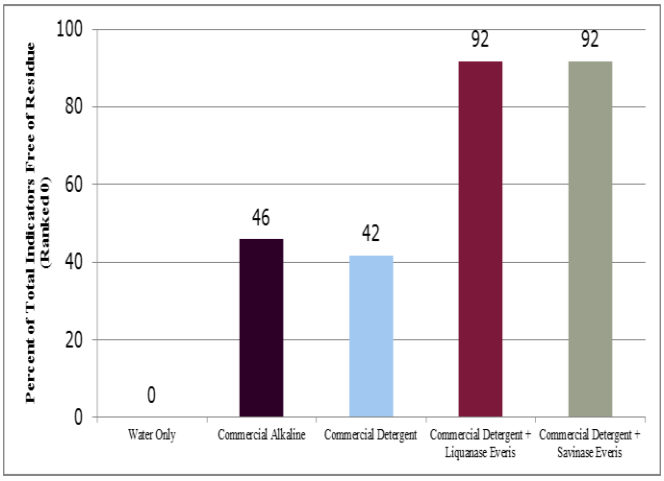

Figure 5. Percent of the indicators in each group that achieved a zero rating (meaning completely clean)

Crile-scissor Results

As for the Crile-scissors, the unwashed controls all tested positive (as expected) for high levels of protein. The Crile-scissors soiled with the commercially available test soil were contaminated with protein levels ranging from 2937 to 8491 µg of protein per scissor while those soiled with the blood ranged from 3687 to 16,067 µg of protein per scissor. The scissors cleaned with water, alkaline detergent and the detergent with 5% Savinase Everis 900 L were all found to have <40 µg (limit of detection) of protein per scissor.

Only three Crile-scissors treated with a cleaning agent had detectable protein levels above 40 µg. In this group, one pair of scissors soiled with blood and treated with the detergent without enzymes had 102 µg of residual protein. The other two scissors cleaned with the detergent containing 5% Liquanase® Everis 900 L were found to have low levels of residual protein (just above limit of detection). Of those cleaned with Liquanase® Everis, the scissor that was soiled with the commercially available test soil was found to have 45 µg of residual protein while the one soiled with blood was found to contain 48 µg of residual protein.

Discussion

The results from the commercially available indicators clearly demonstrated the benefits of adding enzymes (proteases) to a detergent to improve cleaning performance. Adding proteases to a commercial detergent had a substantial impact on cleaning performance. The cumulative rank index for the two enzymatic detergents was 97% while neither the detergent base nor the alkaline detergent reached 90%. In terms of the total number of indicators cleaned, over 90% of those treated with enzymatic detergents were cleaned while the detergent base and the alkaline cleaner could not even reach the 50% mark. While mechanical action and temperature played a role in reducing the organic debris they were not sufficient enough to completely clean the indicators as expected. The results from the manually soiled Crile-scissors were less conclusive. The test soils applied to the scissors did not represent real-world conditions since the mechanical action and temperature inside the WD were enough to remove the organic soil from all but three of the scissors.

While the study was relatively small, the overall results make it clear that the use of enzymes in medical device reprocessing using a washer disinfector have an advantage over alkaline cleaners. Certainly further investigation is warranted by expanding the test conditions (time, temperature) and treatments.

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