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Study on Cleanliness of Loan Instruments by Adenosine Triphosphate

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Introduction: Loan Instruments (LI) is unavoidable in orthopedic implant surgery. In the Guideline of Japanese Society for Operating Medicine 2008, it is recommended to wash LIs before and after using in clinical settings and also after returning to suppliers[1]. However, in a report of surveillance, it is mentioned that the cleaning is in fact insufficient to be carried out[2]. Adenosine triphosphate (ATP) measurement of the contaminants on LIs just after receiving from suppliers and after washing in a Japanese hospital was examined in order to evaluate practical cleanliness of LIs.

Methods: From 16 November 2011 to 6 June 2012, We examined 149 LIs immedately after receiving from the suppliers and 157 LIs after washing in clinical settings in Kinki University Hospital on the ATP values by the measurement reagent (UXL100 clean trace™, 3M) and luminometer (3M™ Clean-Trace™ NG Luminometer, 3M). The measured parts were the plain part, the narrow space, inside the connecting part, the tip, crevice, and the uneven part of the instruments. Also we examined the existence of protein and hemoglobin using urinalysis paper.

Results: 7.0% of LIs after washing and 38.9% of LIs immediately after receiving showed more than 100 Relative Light Unit (RLU). More than 100 RLU of ATP values was observed on many of both uneven and even parts immediately after receiving and also after washing. And contaminants were found in the tip and crevice just after receiving, and in narrow space and crevice after washing. Most of them, however, were not found visually. In the result of observation with urinalysis paper, weak correlation of hemoglobin and ATP values was identified.

Discussion: The ATP measuring is said as the judging method for the instrument contaminants in routine work[3]. But the common standard value is not shown by the supplier. Therefore, it is crucial to determine a standard value in each medical facility. From those results of our investigation, more than 100RLU is decided to be the standard value in Kinki University hospital.

The contaminants in crevice and on uneven parts of LI cannot be recognized visually. So chemical evaluation is required. In the results of ATP measurements, 100 RLU values were observed on many uneven parts. Therefore, the uneven part can serve as the index of contamination evaluation.

The swab stick for ATP measurement was too large for a crevice. For the evaluation of such small parts, a suitable investigation tool must be developed in the future.

Correlation between urinalysis paper and ATP values was not significant. However, urinalysis paper can evaluate a mild contamination[4] and is acceptable as a cheap and simple method.

Conclusion: Rather higher rate of contaminations were found among both LIs immediately after receiving from suppliers and after washing in clinical settings, however, they were not easily found visually. A further careful study is necessary on the residual contaminants of LIs. It is required for contaminant evaluation of LIs to choose the suitable way for the shape of the instruments and to evaluate the index instruments among LI set as well.

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Study on the reliability of Pouch with a side gusset type of sealing quality

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Objectives: In the result of previous study on one thousand of used pouches to test the unpeeled sealing opposite to the opened, 148 had leaked channels. One hundred and eight of them were the gusset type of pouches. So this time the sealing assurance of sterilizing pouch after heat sealing is experimentally studied.

Methods: Three kinds of test methods have been employed to check the leak channel in the sealing which are as follows:

1, Blue ink test, before and after steam sterilization.
2, Peel test of the part of the gusset sealing by tensiometer (Strograph®, Toyoseiki).
3, Powder penetration test through sealing part (Possibility of bacterial contamination). The size of powder is 0.2μm in average.

Results:

1. In the result of blue ink test, the pouches heat sealed with lower temperature (180 and 190 ºC) revealed failure of sealing as shown in Figure 1.

Figure 1. Comparison of sealing temperature: No. of failed/Total tested

Comventional Type Sealer			
Temperature	Pouch width	Sterilization	
		Before	After
180℃	15cm	10/10	10/10
190℃	15cm	0/10	10/10
200℃	15cm	0/10	0/10
180℃	30cm	10/10	10/10
190℃	30cm	4/10	8/10
200℃	30cm	0/10	5/10

Sealer conditions / Pressure time: 3 Stop time: 3 (1≈1.7sec)

2. In the results of peel test, some leak channels were shown in the gusset parts.
3. In the results of powder tests, powder leakages were demonstrated by negative pressure through artificially made channels in the heat sealed parts by surgical suture.

Conclusion: No less than 200ºC should be necessary for heat sealing of sterilization pouches. The gusset part apt to leave the failed leak channel when heat sealed without special attention. The leak channels after sealing can be revealed by fine powder tests.
Heat sealing methods should be reevaluated to obtain the sealing assurances of sterilization pouches.

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The Influence of Low Temperature Sterilisation on Plastic Surface

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Abstract

Background: The results of our previous studies (Yoshida & Kobayashi, 2013) revealed various problems concerning to hydrogen peroxide (HP) gas sterilisation, such as problems of environmental exposure of higher concentration, residual HP on sterilised items, deterioration of the items, false reaction of the chemical indicator (CI), and residual hydrogen peroxide on plastic materials after sterilisation. In addition to these problems, this time the suspected structural influence of low temperature sterilisations are studied.

Objective: To examine plastic surfaces after low temperature sterilisation.

Methods: The influence of two kinds of hydrogen peroxide sterilisations, ethylene oxide gas sterilisation and low temperature steam formaldehyde sterilisation on the surface of 11 kinds of plastic panels was evaluated by scanning electron microscope (SEM). The Plastic panels tested were polyetherimide, polyethylene, polytetrafluoroethylene, nylon 6, nylon 66, polyethyleneterephthalate, polyetheretherketone, thermoplastic polyurethane, polymethylmethacrylate, polypropylene and polycarbonate.

Results: HP gas sterilisations induced crack, crackle, or bumpy, rugged or lumpy change on the most of plastic surfaces, though no changes were found on the surfaces before sterilisation procedures.

Conclusion: Both HP sterilisations induced the structural changes of the surfaces of plastic materials. However, the cause has not been identified yet. A further study is required to identify the cause.

Keywords: Low Temperature Sterilisation, Plastic Surface, Scanning Electron Microscope