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The Utility of Water Leak Test in Evaluating the Functionality of Sterilization Containers

Hajar Daoudi[1,2*], Soumaya Arbai[1], Safaa El Marnissi[1,2], Jaouad El Harti[1,2], Soufiane Derraji[2], Mina Ait El Cadi[1,2]

Corresponding Author: Hajar Daoudi

[1]Ibn Sina Hospital, Ibn Sina University Hospital Center, Rabat-Morocco
[2]Faculty of Medicine and Pharmacy of Rabat, Mohamed V University, Rabat-Morocco

Abstract:
Introduction: The reprocessing of reusable medical devices is a specialized process that requires careful management and control of various preparation steps [1].The sterile state of a medical device can only be maintained when the integrity of the sterile barrier is not compromised [2].
Materials & Methods: This study employed a prospective descriptive observational design. An inventory was conducted to list all the containers used in the visual integrity check process and water leak test.The detection of a leak necessitated the replacement of the container's seal. If the leak persisted, the entire container was replaced.
Results & Discussions: The results of the water leak test showed that out of the 55 tested containers, 25 were positive, indicating a positivity rate of 45% and requiring maintenance or replacement interventions. Comparing the results revealed significant differences in the positivity rates, ranging from 8% to 28%, which can be attributed to variations in technical and educational resources among different facilities.
Conclusion: Our findings highlight the need for corrective actions, such as personnel training on proper usage, maintenance, and regular systematic inspection of the containers. Additionally, developing instructions for proper packaging and sealing is essential to address the identified issues.
Keywords: Water leak test, Sterilization container, Reprocessing, Reusable medical devices.

Introduction

The reprocessing of reusable medical devices is a specialized process that requires mastery and control of various preparation stages. It consists of six phases: pre-disinfection, cleaning, packaging, sterilization, release of the sterilization load, and storage or direct delivery to the department [1].

The sterile condition of a medical device can only be maintained when the integrity of the sterile barrier system is not compromised. Indeed, no microbiological sampling can be performed as it would break the sterile state [2]. In the case of flexible packaging (pouches, wraps, or sheets), tears or punctures compromising sterility are easily identifiable. However, for reusable containers, assessing packaging integrity, especially just before use in the operating room, is more challenging [1] .According to Good Hospital Pharmacy Practices, "The packaging must be compatible with the sterilization process, maintain sterility until use, and allow aseptic extraction of the device" [3]. For this reason, functionality tests are performed prior to packaging to assess the performance of these packages before sterilization. When these tests yield negative results, the containers are removed from the production cycle and require maintenance before reuse. In France, a testing method to evaluate the seal tightness of container tank/lid closure is described in a normative document [4]. Currently, this water leak test, practiced in some healthcare facilities, is not recognized by container manufacturers [5]. The objective of this study is to verify the maintenance of the sterile barrier system integrity of containers used in the operating theater of the central operating block of Ibn Sina University Hospital in Rabat. Following the results of a national survey showing that 29% of containers in healthcare facilities in France and 17% in Switzerland tested positive in the water leak test [6, 7], the question arose naturally whether the presence of leaks in the tank/lid junction potentially correlated with the risk of losing sterility in a sterilization container.

Materials & Methods:

This was a descriptive observational study conducted in the sterilization department of the central operating block of Ibn Sina University Hospital over a period of 3 weeks in 2022. First, an inventory was conducted on all containers used in the sterilization process, categorizing them by size, type of procedure, and brand.

Subsequently, the different containers underwent a visual inspection of joint integrity and a water leak test following the protocol mentioned in the previous paragraph. Both tests were conducted by three operators over a period of 3 weeks, depending on the availability of containers.

In case of detecting a leak, the joint was replaced, and if the leak persisted, the container was replaced.

Results:

The results of the water leak test conducted on all the containers are presented in the following table:

Table 1: Results and data of the water leak test.

Number	Designation	Container Type (Valve or Filter)	Brand	Water Leak Test
1	S1	Valve	WAGNER	Positive
2	S2	Valve	WAGNER	Positive
3	S3	Valve	WAGNER	Positive
4	S4	Valve	WAGNER	Positive
5	S5	Valve	WAGNER	Positive
6	G2	Valve	AYGUN	Negative
7	G3	Valve	AYGUN	Negative
8	G4	Valve	ÄYGUN	Negative
9	G5	Valve	AYGUN	Negative
10	G6	Valve	AYGUN	Negative
11	Procto1	Valve	WAGNER	Positive
12	Procto2	Valve	WAGNER	Negative
13	Procto3	Valve	WAGNER	Positive
14	L11	Valve	AYGUN	Negative
15	L3	Valve	AYGUN	Negative
16	Laparo4	Valve	AYGUN	Negative

According to the results, out of the 55 tested containers, 25 were positive in the water leak test, accounting for 45% of the containers, while 55% were negative [Fig. 3]. These positive containers required maintenance or replacement. The observed leaks were significant and immediate, affecting at least one side of the container.

The graphs below illustrate the results of the table in different distributions. The containers from the Wagner and Ceylan brands, which were acquired earlier, have the highest proportion of positive test results [Fig. 5]. On the other hand, the Aygun brand, which is newly acquired, represents only 9% of the containers that tested positive for water leaks [Fig. 5].

When considering the distribution by container type, valve containers account for more than half of the positive tests, with a percentage of 64%, compared to 36% for filter containers [Fig. 4].

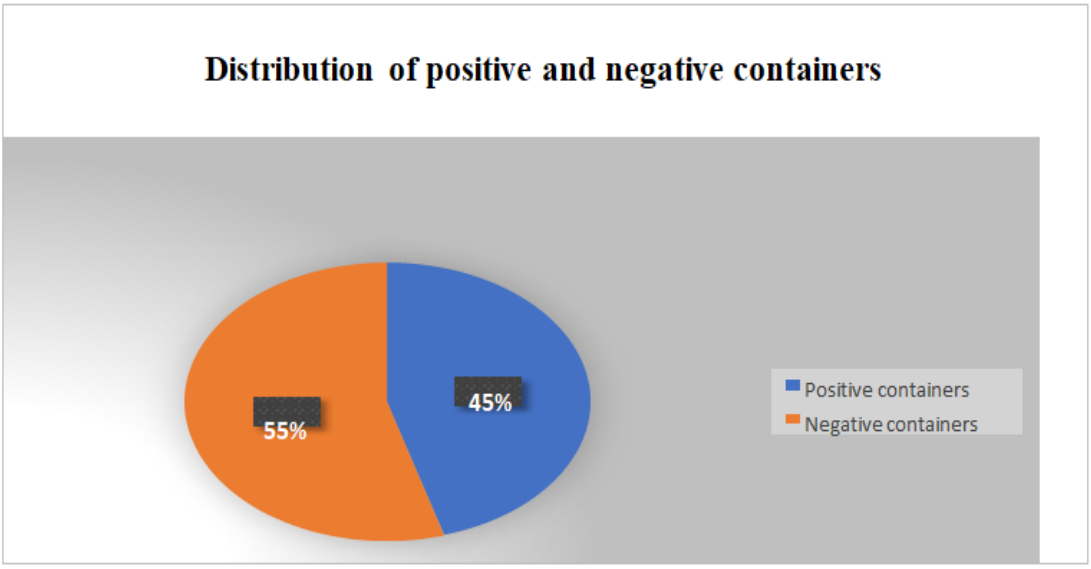

Figure 3: Distribution of positive and negative containers.

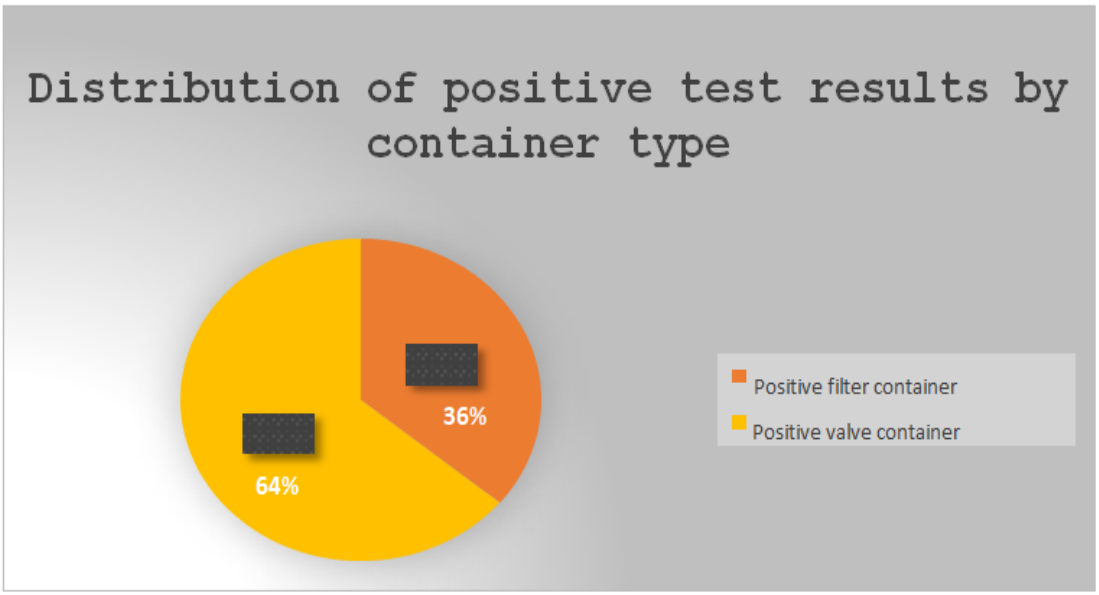

Figure 4: Distribution of positive test results by container type

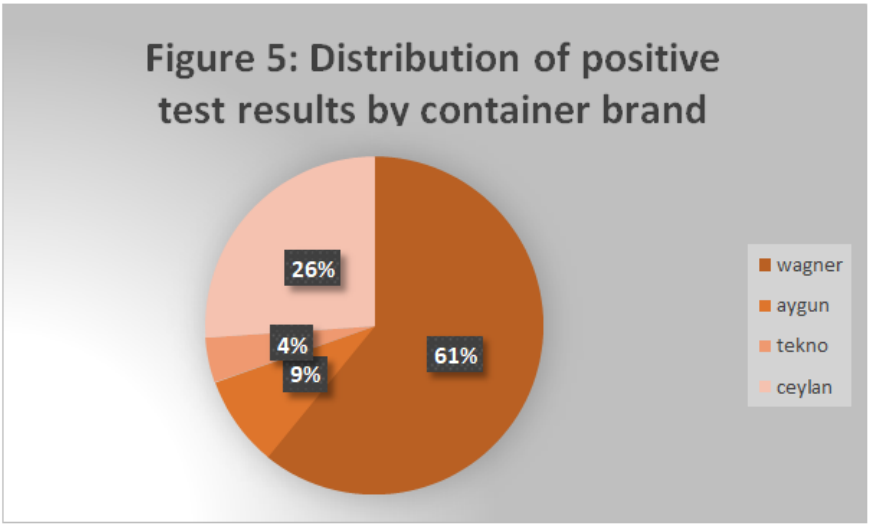

Figure 5: Distribution of positive test results by container brand.

Discussion:

The central sterilization service of Ibn Sina Hospital has the mission of delivering to care services, intensive care units, and operating rooms a product devoid of any pathogenic germs, known as sterilized, in accordance with current standards and regulations.

For this reason, the packaging stage of cleaned medical devices must ensure the protection of the equipment from any recontamination through packaging that allows:

- Maintaining sterility until the use of the medical device.
- Aseptic removal of the medical device.

The materials used for packaging medical devices must comply with current standards and specifications, and the equipment used must be maintained and checked for:

- Sealer control (temperature and sealing force).
- Scheduled maintenance of containers.

According to the EN ISO 11607-1 standard, the person who packages and sterilizes medical devices must receive specific training to ensure an aseptic presentation of the medical device and validate the sterile barrier system for each medical device.

From the user's perspective, difficulties persist in the field:

- Adapting the instructions for use to the service's practice.
- Developing procedures or work instructions (specific to reprocessing, control, and maintenance).
- Lack of means for proper maintenance of packaging equipment and materials.
- Lack of training and ongoing monitoring of practices and operation traceability.

In our study, we attempted to measure the impact of all these constraints on the condition of the containers used in the sterilization process. To do this, we conducted a water leak test on a total of 55 containers used for various procedures, as listed in Table 1.

The results obtained show that nearly half of the containers tested positive for water leakage, with 25 positive containers out of a total of 55, representing a percentage of 45% [Fig. 3]. Comparing these results to a study conducted at the Nord Deux-Sèvres Hospital Center in Bordeaux [10], where 37% of containers tested positive for water leakage, there is a difference of 8%. Another study conducted in France showed that 29% of containers had water leaks in different establishments, compared to only 17% in Switzerland [6; 7].

The comparison of these different results shows that we have the highest percentage with respective differences of 8%, 16%, and 28%, which is significant and understandable if we assume the gap between the different technical and educational means among these different institutions.

The distribution of positive results in the water leak test according to different brands [Fig 5]

shows that the Wagner brand has the highest percentage of containers with water leaks at 61%, followed by the Ceylan brand at 26%. This can be explained by the age of these containers, the lack of periodic preventive and corrective maintenance, as well as the lack of educational and material means for maintenance (inappropriate and defective loading and unloading modules exposing containers to the risk of damage, lack of instructions regarding proper closure and sealing of containers, improper loading of the autoclave exposing containers to the risk of deformation due to weight).

Considering the results obtained according to the type of container, it can be observed that containers with valves are more prone to water leaks and integrity failure, with a percentage of 64% [Fig. 4] compared to containers with replaceable filters. This may be due to the predominance of valve containers over filter containers in the technical platform and, secondarily, to the lack of knowledge of the valve integrity verification procedure or misuse during the cleaning and sealing of containers.

Conclusion:

In daily practice, it is not possible to verify the sterile status of each surgical set before its use. Therefore, to ensure the sterility of the final product, the steps of the sterilization process must be perfectly controlled, and a final check of the packaging integrity must be performed just before the use of the sterile product. In the case of flexible packaging, it is relatively easy to detect tears or perforations that compromise the sterility of the packaged device. However, for reusable containers, there are no similar controls to identify integrity breaches. Therefore, it is necessary to perform functionality checks before each reassembly to ensure their performance is maintained [8].

The water leak test is useful for identifying and correcting seal leakage issues during container maintenance. However, conducting this test as a routine practice outside of maintenance is challenging due to its time-consuming nature and the logistical challenge of managing non-leakproof containers. Consequently, containers that test positive in the water leak test should be removed from the reprocessing cycle and undergo corrective maintenance before reuse. For newly acquired containers, the development of a preventive maintenance schedule is a viable solution.

In addition to these considerations, corrective actions should be taken, such as providing personnel training on the proper use, maintenance, and regular systematic inspection of containers. Developing instructions for proper packaging and sealing is crucial, along with expressing the need for equipment and resources to ensure proper maintenance and transportation of containers.

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