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Detecting Steam Sterilizer Air Leaks Pre-Assembled Process Challenge Devices: A Comparison Study

Abstract

Background: The presence of air in the sterilizer chamber is a common cause of steam sterilization process failures. This study investigated the ability of two different commercially available Process Challenge Device (PCD) to consistently detect air leaks in pre-vacuum steam sterilization cycles.

Method: Two test conditions were investigated: Control Cycles, which did not have an air leak; and Air Leak Cycles, in which a valve was used to deliberately create an air leak. Bowie-Dick tests were run in each test condition. Pre-assembled PCDs having two different designs, one a pre-assembled wrapped pack containing multiple layers of a fibrous and porous material enclosing the indicators and the other a plastic base (which contains the indicators) with a foil lid, were evaluated. Both PCDs contained a biological indicator (BI) and a chemical integrator (CI). Three replicate Control Cycles and nine replicate Air Leak Cycles were run. Each test cycle included three PCDs of each design.

Results: The Control Cycles had passing Bowie-Dick test results. In both PCD designs, all BIs were negative and all CIs had Accept results. A significant difference in the results from the two PCD designs was not observed in the Control Cycles ($p=1.000$). The Air Leak Cycles had failing Bowie-Dick test results, indicating a significant air leak. 26/27 (96%) of the BIs from the wrapped PCD were positive, indicating a sterilization process failure, while 0/27 (0%) of the BIs in the plastic base/foil lid design PCD were positive. These results are statistically significantly different ($p<0.0001$). 25/27 (93%) of the CIs in the wrapped PCD had Reject results, indicating a sterilization process failure, while 0/27 (0%) of the CIs in the plastic base/foil lid PCD design had Reject results, also a statistically significantly different result ($p<0.0001$).

Conclusion: Not all pre-assembled PCD designs are capable of consistently detecting air leaks. In this study, a commercial PCD comprised of multiple layers of fibrous material was able to detect a serious air leak failure far more consistently than a commercial PCD comprised of a plastic base and foil lid.

Introduction

Process challenge devices (PCDs, also called test packs) are used to assess the performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed.[1] Effective performance of a steam sterilization process requires the presence of dry saturated steam, which is only possible if there is virtually no air remaining in the sterilizer chamber during the process.

Air in the chamber may be the result of an inadequate vacuum system that is unable to remove all the air from the chamber during the conditioning phase; or, it may be the result of air leaking back into the chamber through faulty plumbing, valves, or gaskets during sub-atmospheric periods of the sterilization process.

PCDs used to monitor steam sterilization processes may use different physical designs to create the challenge to the sterilization process, but it is imperative that, regardless of the design, the PCD devices can consistently detect sterilization process failures related to the presence of air in the sterilizer chamber, such as in an air leak situation.

This study compares the ability of two different types of commercially available PCD designs to consistently detect air in a sterilizer chamber. A valve was used to deliberately create an air leak during the sterilization process. The first design is a pre-assembled wrapped pack containing multiple layers of a fibrous and porous material (paper index cards) enclosing the indicators. The fibrous layers entrap air, thus challenging the sterilization process by interfering with the saturated steam's penetration to the indicators inside the pack (see Figure 1). The second design is a pre-assembled plastic base (which contains the indicators) with a foil lid (see Figure 2). A short channel in the plastic base is used to create the challenge to air removal and steam penetration.[2] Both PCD designs contain a self-contained biological indicator and a Type 5 integrating indicator.

Figure 1: Pre-Assembled Wrapped Pack PCD Design

Figure 2: Pre-Assembled Plastic Base with Foil Lid PCD Design

All Air Leak Cycles were created by opening the micro-metering valve to the set-point position required to create the desired leak rate. All test cycles were run with 4 pre-vacuum pulses and an exposure phase temperature set point of 132.2°C (270°F).

Method

Test Sterilizer

All tests were completed in an AMCSO® Eagle® Model 3013-C Vacamatic steam sterilizer equipped with a port fitted with a micro-metering valve which allows introduction of precision air leaks during the sterilization process. Control Cycles with no air leak were run with the micro-metering valve in the closed position, to demonstrate the integrity of the sterilizer chamber.

Bowie-Dick Tests

The presence of air in the sterilizer chamber was evaluated using two commercially available, pre-assembled Bowie-Dick type test packs:

1. 3M™ Comply™ Bowie-Dick Plus Test Pack 00135LF, manufactured by 3M Company, St. Paul, MN.
2. Steris™ DART® Daily Air Removal Test, manufactured by Steris Corporation, Mentor, OH.

Process Challenge Devices (PCDs)

Two different commercially available, pre-assembled PCD designs were evaluated. Three lots of each design, each having a different lot of biological indicators, were used.

1. The layered fiber PCD design was represented by the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V (manufactured by 3M Company, St. Paul, MN). These PCDs contain a biological indicator (3M™ Attest™ Super Rapid Readout Biological Indicator 1492V) and an ISO Type 5 integrating indicator (3M™ Comply™ SteriGage™ Steam Chemical Integrator).
2. The plastic base/foil lid PCD design was represented by the Steris™ Verify® Assert™ STEAM Process Challenge Device for Dynamic Air Removal (manufactured by Steris Corporation, Mentor, OH). These PCDs also contain a biological indicator (Steris™ Verify® Assert™ Self Contained Biological Indicator) and an ISO Type 5 integrating indicator (Steris™ Verify® Steam Integrating Indicator).

Test Procedures

Control Cycles — No Air Leaks

Control Cycles were run with the micro-metering valve in the closed position. Bowie-Dick test cycles (132.2°C, 4-pulse, 3.5 minute hold time, 1 minute dry time) were run to verify that the sterilizer did not have any inherent air leaks with the valve in the closed position. Each Bowie-Dick test pack was run in a separate test cycle, placed in an empty chamber over the drain, and results interpreted according to the manufacturers' instructions for use.

After the Bowie-Dick testing, the two pre-assembled PCD designs were tested in Control Cycles (No Air Leak), to verify their performance in standard sterilization cycles. The PCDs were tested by placing three replicates of the layered fiber PCD design and three replicates of the plastic base/foil lid design in the lower level of the chamber. Each test set contained a sample of each lot of PCD. Each test set was replicated three times. Pre-vacuum cycles were run (132.2°C, 4-pulse, 4 minute exposure time, no dry time), and the PCDs were then removed from the chamber. The monitoring products were retrieved from the PCDs and the chemical integrator results were documented. The 3M™ Attest™ 1492V biological indicators were activated and incubated per the manufacturer's instructions in an 3M™ Attest™ Auto-reader 490. The Steris™ Verify® Assert™ Self Contained Biological Indicators were activated and incubated per the manufacturer's instructions in a Steris™ Verify® Incubator for Steris™ Assert™ SCBIs (Catalog # LCB030).

Air Leak Cycles

Air Leak Cycles were created by opening the micro-metering valve to a constant setpoint position required to create the desired air leak rate. The Bowie-Dick test cycles (132.2°C, 4-pulse, 3.5 minute exposure time, no dry time) were run with the micro-metering valve in the setpoint position to assess the presence of an air leak. The Bowie-Dick tests were conducted in separate test cycles, placed in an empty sterilizer Chamber over the drain, and results interpreted according to the manufacturers' instructions for use.

Both pre-assembled PCD designs were then tested in the Air Leak Cycles in the same manner as in the Control Cycles testing. Each test set (three replicates of the layered fiber PCD design and three replicates of the plastic base/foil lid PCD design) was replicated nine times.

Results

Control Cycles — No Air Leak

Bowie-Dick Test Results — Control Cycles

Bowie-Dick type tests completed on Control (non-air leak) Cycles confirmed that the closed micro-metering valve resulted in no measurable air leaks and passing Bowie-Dick Tests. The results are summarized in Table 1. Scans of the passing Bowie-Dick test sheet or strip from the Control Cycles are provided in Figure 3.

Figure 3: Bowie-Dick Test Results — Control Cycle (No Air Leak)

Left: 3M™ Comply™ 00135LF Test Sheet; Right: Steris™ DART® Test Strip

PCD Test Results — Control Cycles

The results of the monitoring products contained in the PCDs tested in Control Cycles are provided in Table 2 (Biological Indicator Results) and Table 3 (Chemical Integrator Results). Biological indicator results are reported as Negative or Positive, as determined by the respective incubator/reader. All biological indicators were negative and results from the McNemar's test for the data in Table 2 did not show statistically significant differences between the two PCD designs (p=1.000). Chemical integrator results are reported as Accept or Reject. All chemical integrators in both PCD designs had Accept results and analysis using McNemar's test for the data in Table 3 did not show statistically significant differences between the two PCD designs (p=1.000).

Table 1 :Bowie-Dick Test Results — Control Cycles (No Air Leak)

Test Type	Lot #	Result
3M™ Comply™ Bowie-Dick Plus Test Pack 00135LF	202003CH	Pass
Steris™ DART® Daily Air Removal Test	M17059	Pass

Table 2: Biological Indicator Results — Control Cycle (No Air Leak)

Biological Indicator	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V			Steris™ Verify® Assert™ Self-Contained Biological Indicator in Steris™ Verify® Assert™ STEAM PCD for Dynamic Air Removal Cycles		
BI Lot #	**3335PJ**	**2019-10AJ**	**2019-10NL**	**20190801A**	**20191103**	**20191108**
Cycle 1	Negative	Negative	Negative	Negative	Negative	Negative
Cycle 2	Negative	Negative	Negative	Negative	Negative	Negative
Cycle 3	Negative	Negative	Negative	Negative	Negative	Negative

Table 3: Chemical Integrator Results — Control Cycle (No Air Leak)

Chemical Integrator	3M™ Comply™ SteriGage™ Chemical Integrator in 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V			Steris™ Verify® Steam Integrating Indicator in Steris™ Verify® Assert™ STEAM PCD for Dynamic Air Removal Cycles		
CI Lot #	**202103CM**	**202102CH**	**202102CH**	**2019-08-01**	**2020-10-01**	**2020-10-01**
Cycle 1	Accept	Accept	Accept	Accept	Accept	Accept
Cycle 2	Accept	Accept	Accept	Accept	Accept	Accept
Cycle 3	Accept	Accept	Accept	Accept	Accept	Accept

Air Leak Cycles

Bowie-Dick Test Results — Air Leak Cycles

The results from the Bowie-Dick type tests completed on Air Leak Cycles confirmed that the open micro-metering valve resulted in significant air in the sterilizer chamber as evidenced by failing Bowie-Dick tests. The results are summarized in Table 4. Scans of the Bowie-Dick test sheet/strip from the Air Leak Cycles are provided in Figure 4.

Figure 4: Bowie-Dick Test Results — Air Leak Cycle

Left: 3M™ Comply™ 00135LF Test Sheet; Right: Steris™ DART® Test Strip

PCD Test Results — Air Leak Cycles

The results of the indicators contained in the PCDs tested in Air Leak Cycles are provided in Table 5 (Biological Indicator Results) and Table 6 (Chemical Integrator Results). Again, biological indicator results are reported as Negative or Positive. 26/27 (96%) of the BIs from the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V were positive, indicating a sterilization process failure, while 0/27 (0%) of the BIs processed in Steris™ Verify® Assert™ STEAM PCD for Dynamic Air Removal Cycles were positive. These results are statistically significantly different when compared using McNemar's test ($p<0.0001$).

Table 4: Bowie-Dick Test Results — Air Leak Cycle

Test Type	Lot #	Result
3M™ Comply™ 00135LF Test Sheets	202003CH	Fail
Steris™ DART® Test Strip	M17059	Fail

Table 5: Biological Indicator Results — Air Leak Cycle

Biological Indicator	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V			Steris™ Verify® Assert™ Self-Contained Biological Indicator in Steris™ Verify® Assert™ STEAM PCD for Dynamic Air Removal Cycles		
BI Lot #	3335PJ	2019-10AJ	2019-10NL	20190801A	20191103	20191108
Cycle 1	Positive	Positive	Positive	Negative	Negative	Negative
Cycle 2	Positive	Positive	Positive	Negative	Negative	Negative
Cycle 3	Positive	Positive	Positive	Negative	Negative	Negative
Cycle 4	Positive	Positive	Positive	Negative	Negative	Negative
Cycle 5	Positive	Positive	Positive	Negative	Negative	Negative
Cycle 6	Positive	Positive	Positive	Negative	Negative	Negative
Cycle 7	Positive	Negative	Positive	Negative	Negative	Negative
Cycle 8	Positive	Positive	Positive	Negative	Negative	Negative
Cycle 9	Positive	Positive	Positive	Negative	Negative	Negative
% Process Failures Detected	96			0		

Table 6: Chemical Integrator Results — Air Leak Cycle

Chemical Integrator	3M™ Comply™ SteriGage™ Chemical Integrator in 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V			Steris™ Verify® Steam Integrating Indicator in Steris™ Verify® Assert™ STEAM PCD for Dynamic Air Removal Cycles		
CI Lot #	**202103CM**	**202102CH**	**202102CH**	**2019-08-01**	**2020-10-01**	**2020-10-01**
Cycle 1	Reject	Reject	Reject	Accept	Accept	Accept
Cycle 2	Reject	Reject	Accept	Accept	Accept	Accept
Cycle 3	Reject	Reject	Reject	Accept	Accept	Accept
Cycle 4	Reject	Reject	Reject	Accept	Accept	Accept
Cycle 5	Reject	Reject	Reject	Accept	Accept	Accept
Cycle 6	Reject	Reject	Reject	Accept	Accept	Accept
Cycle 7	Reject	Accept	Reject	Accept	Accept	Accept
Cycle 8	Reject	Reject	Reject	Accept	Accept	Accept
Cycle 9	Reject	Reject	Reject	Accept	Accept	Accept
% Process Failures Detected	**93**			**0**		

Chemical integrator results are reported as Accept or Reject. 25/27 (93%) of the 3M™ Comply™ SteriGage™ chemical integrators from the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V had Reject results, indicating a sterilization process failure, while 0/27 (0%) of the Steris™ Verify® Steam Integrating Indicators in the Steris™ Verify® Assert™ STEAM PCD for Dynamic Air Removal Cycles had Reject results. These results are statistically significantly different when compared using McNemar's test ($p<0.0001$).

Overall, the wrapped pack PCD design detected the process failure caused by the presence of the significant air leak 96% of the time while the plastic base/foil lid design PCD detected this failure 0% of the time.

Discussion

Saturated steam is a critical requirement for successful steam sterilization. According to Dion, *"Insufficient air removal, sterilization chamber vacuum leaks and poor steam quality (excess non-condensable gases) are the most common causes of sterilization failures."*[3] Air in the chamber might be the result of an inadequate vacuum system that is unable to remove all of the air from the chamber during the conditioning phase, or it may be the result of air leaking back into the chamber during sub-atmospheric periods in the sterilization process.

Per Joslyn: *"Common causes of air in the sterilizing chamber with vacuum sterilizers are air leaks through mechanical components such as valves and door gaskets, or fatigue cracks in piping. Even with diligent equipment check-out efforts, the sterilizer may develop an air leak between tests or exhibit intermittent leak problems that compromise proper sterilization."*[4]

Standards and recommended practices for steam sterilization recommend that a Bowie-Dick type air removal test be performed on each pre-vacuum sterilizer at the beginning of each day,[5] to provide an assessment of the air removal performance and chamber integrity of the sterilizer at that single point in time. However, these single daily empty chamber tests will not provide information about air removal problems or air leaks that might occur during subsequent sterilization cycles throughout the day.

Process challenge devices, or test packs, can be used in every sterilization cycle to provide an ongoing assessment of the efficacy of the sterilization process. These PCDs should provide a rigorous challenge to the sterilizer and must be able to consistently detect faults in the sterilization process. This study evaluated the ability of two pre-assembled PCD designs to consistently detect a major fault in a sterilization process: air leaking into the sterilization chamber.

The Bowie-Dick type tests both gave passing results indicating appropriate air removal for the Control Cycles, which were standard pre-vacuum sterilization cycles run without an air leak. As expected, the data from the BI PCDs tested in this study showed that all indicators in both PCD designs provided passing results in the Control Cycles.

The failing results of the two Bowie-Dick type tests clearly demonstrated the fault condition created during the Air Leak Cycles. These test results confirmed a significant air leak in the sterilizer chamber that would be considered a process failure.

The PCD data revealed a statistically significant difference in the ability of the two designs to detect a significant air leak. The data from the layered fiber design PCDs in the Air Leak Cycles showed that this design was able to more consistently detect this process failure. The biological indicators in the fibrous layer PCD detected this process failure 26/27 times (96%), and the chemical integrating indicators in these PCDs detected the failure 25/27 times (93%). The test data from the plastic base/foil lid PCD design indicated that these devices did not consistently detect this sterilization process failure. Both biological and chemical integrating indicators in the plastic base/foil lid PCD detected the process failure 0/27 times (0%).

Differences in the observed performance of the two pre-assembled PCDs are most likely related to the difference in the designs, and how they create a challenge to the sterilization process. It is possible that the multiple layer fiber pack PCD design allows air re-entering the chamber via a leak to readily penetrate back into the test pack, creating non-saturated steam conditions inside the pack which are consistently and successfully detected by the indicators. It should be noted that this PCD design is reflective of the traditional layered PCD design described in standards (i.e., the AAMI 16-towel PCD).[6]

Limitations

While we speculate that the difference in test results observed during the Air Leak Cycles can be attributed to the differences in the design of the two pre-assembled PCDs, this study does not facilitate determination of whether the performance of the BIs and CIs themselves is also a contributing factor. A study investigating the performance of the monitoring devices in an AAMI 16-towel PCD in the same failure mode, the Air Leak Cycle condition, could help determine this.

Conclusion

Not all PCD designs are capable of consistently detecting air leaks. In this study, a pre-assembled, commercial PCD comprised of multiple layers of fibrous material was able to detect a serious air leak failure far more consistently than a pre-assembled, commercial PCD having a plastic base/foil lid design. While current standards and regulatory organizations do not require an air leak test for BI PCDs, detection of air leaks is critical to effective quality control of steam sterilization processes, and therefore to patient safety.

References

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