Current reference devices for hollow instrument loads as defined in standards are not a valid steam penetration test

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In hospitals steam sterilization is an important aspect of infection prevention. Testing of steam penetration is a necessity. In some cases a hollow helix shaped Process Challenge (PCD) device is suggested as steam penetration test for hollow instruments. Since the introduction of these hollow A, hollow load, helix, or helix shaped PCD in standards, discussions about the use of these PCDs are ongoing. Conclusive experimental data on these hollow PCDs was not found in the literature. For the present study a strictly defined helix shaped PCD «reference» device was manufactured. Its performance was tested in a small (11 l) and a large (342 l) test steam sterilizer and compared with the minimum requirements for steam penetration defined in the ISO standards. It was found that this device does not fulfill these minimum requirements. Also these results indicate that hollow A or helix PCDs as presently defined in standards should not be used as steam penetration test in steam sterilization processes. Consequently, PCDs tested against this reference PCD or standard will also not meet the requirements for steam penetration. These PCDs should therefore not be used as steam penetration test for hollow instruments.

KEY WORDS
- hollow instruments
- steam penetration
- PCD
- hollow A
- helix

Introduction

Steam sterilization is an important step in infection prevention for staff, patients, and environment in hospitals. Before starting production in a steam sterilizer it has to be warmed up. After warming up it should be ensured that in a sterilization process all surfaces are exposed long enough to steam sterilization conditions [1, 2, 3].

According to standards the steam penetration capacities of a sterilizer should be tested with a steam penetration test [4]. In Europe, harmonized standards[i] make steam penetration testing mandatory. Necessity of such a test is evident [5]. In the early 1960s Bowie and Dick developed the first steam penetration test [6]. This test was further developed and minimum performance requirements are defined in standards [7, 8, 9].

In current European standards [10] for small sterilizers with Type B and specific Type S processes it is suggested that a so called «Process challenge device for hollow instrument loads (hollow load process challenge device)» can be used as steam penetration test for hollow devices [11]. Often these PCDs are helix shaped and are in practice referred to as helices or helix PCDs (figure 1).

Remarkably this hollow A test is not recognized as steam penetration test in the standard for large steam sterilizers [12]. In this standard, where the device is referred to as hollow load, it is merely an additional test that can be used in periodical testing such as validations. Not only in standard committees for small[ii] and large sterilizers[iii] and chemical indicators[iv] the hollow A tests are still under discussion but also in the literature [13, 14]. Moreover, conclusive experimental evidence supporting the hollow A functionality has to our knowledge not been reported.

Therefore we found it worthwhile to perform experiments to study whether hollow A PCDs [10], hollow load test [11,12] or helix PCDs could be used in steam monitoring, or not.

The condition for steam sterilization of surfaces is the presence of saturated steam at a predetermined temperature [1, 3]. Once these conditions are established they must be maintained for a predetermined time, e. g., saturated steam kept at 134 °C for 3 minutes.

Monitoring and routine tests are used to check and ensure whether or not these steam sterilization conditions are met and maintained. Before starting production a steam penetration test has to show that a

i *http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/, last visited: 24-06-2012*

ii *European Norm Committee Technical Committee 102 Sterilizers for medical purposes Work Group 5 Small sterilizers, in short EN TC 102 WG 5.*

iii *EN TC 102 WG 2/3, Originally the WG 2 develops standards for testing of steam sterilizers andWG3 requirements for steam sterilizers. Currently the working groups are combined.*

iv *International Organization for Standardization Technical Committee 198 WG 6 Chemical Indicators, in short ISO TC 198 WG 6.*

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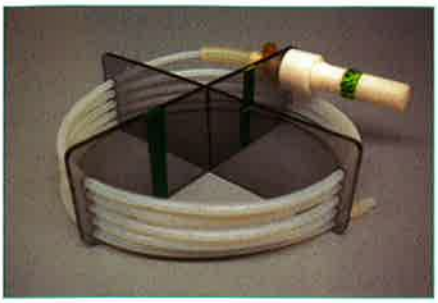

Fig. 1: Hollow A or helix Process Challenge Device as specified in the standards [10,11] and further specified in the TC 198 WG6 documents. The tubing is placed in a holder because tubing bound together may influence the results [16]. In the receptacle a CI can be loaded before use in a process. After a process the CI can be taken out and investigated.

steam sterilizer establishes sterilization conditions and that these conditions are maintained for the predetermined time. In Europe minimum requirements for steam penetration tests are specified in the standards ISO 11140 part 3 and part 4 [7, 8]. These standards make use of a standardized textile test pack.

Standards discriminate between small and large sterilizers [10, 12]. Small sterilizers are defined as sterilizers unable to accommodate a sterilization module (30 × 30 × 60 cm) and have a chamber volume not exceeding 60 l. All other sterilizers are considered as large sterilizers. Standard textile test packs have dimensions of 22 × 30 × 25 cm and may not fit in every small sterilizer. Alternative tests are therefore necessary and are available in the market.

In 1998 hollow A PCDs were introduced in the standards [10, 11]. Currently the ISO Technical Committee 198 Work Group 6 Chemical Indicators (ISO TC 198 WG 6) is preparing a new standard ISO 11140 part 6 to replace the European standard EN 867 part 5 [11] in which the hollow A device is defined. To end ongoing discussions on these devices TC 198 WG 6 started a Round Robin Study (RRS) in the first half of 2009 with a hollow load A device. A RRS is a method in which several laboratories or researchers perform the same experiments independently from each other. The main goal for the ISO TC 198 WG 6 is to find whether or not consistency in results between different labs will be found when the same protocol is used. The protocol specifies the test method, a reference PCD including a Chemical Indicator (CI) and the test processes. This PCD could become a reference device in the standards for testing alternative (commercial) devices. Therefore the Work Group specified a helix shaped PCD with more strict specifications and dimensions than the hollow A currently in the standards [10, 11]. Unfortunately, data from this RRS is not yet available in the public domain.

European standards specify minimum performance requirements for steam penetration in the ISO 11140 part 4 [8]. It is essential that a reference hollow A PCD meets these minimum performance requirements. In the present study the reference hollow A PCD is compared with the performance requirements for steam penetration tests. After describing the material, the used equipment and protocol in the section Material and Method, the results are presented in the Results section. In the Discussion section these results are discussed and some conclusions will be drawn.

Material and Method

Hollow A PCDs were tested in a small and a large test steam sterilizer (figure 2). After establishing the process that gave a reproducible pass result with the hollow A PCDs, this process was tested with a standard towel pack in the large sterilizer. In figure 3 a schematic representation of the used processes is depicted. It is based on the B1 test cycle as defined the ISO 11140 part 4 [8]. Between different test processes only the Vacuum Control Points (VCPs) were changed. Tests in both sterilizers started with VCPs of 400 mbar. With these VCPs no color changes of the CI were observed.

Tests for each experimental condition were repeated at least in 9 times. Next the VCPs were decreased to find the point were reproducible full coloration of the CIs was found. Using this process standard towel packs were tested in the large sterilizer. One of the fail conditions in the standards is that at the time the chamber reference temperature (T_c) attains the set temperature (T_r) the temperature measured in the standard test pack (T_p) should show a temperature depression, ($T_c - T_p$), of 2 K or greater [8].

To avoid this fail condition in the performed tests, all temperatures measured in the towel test pack (T_p) must be between the 132 °C and 134 °C at the moment that the sterilizer chamber temperature (T_c) reaches 134 °C. This requirement can also be written as: at the start of the exposure phase $T_c - T_p \leq 2$ °C has to be satisfied.

The used test sterilizers were of the brand Lautenschläger (Cologne, Germany): Type 219 with volume of 11 l and a Type 3119/4 STE test sterilizer with a volume of 342 l. Originally the Type 219 is a CIER/BIER [15] but it is modified and can be used as a test sterilizer as well. Both sterilizers and their steam supply meet the requirements in the applicable standards [8].

The Process Challenge Devices (PCDs) used in the present study were hollow A helix shaped PCDs (figure 1) and standard towel packs as defined for testing steam penetration tests [8]. The construction of the Hollow A PCD is based on descriptions in standards [10, 11] which are further specified in the working documents of ISO TC 198 WG 6 for the Round Robin Study. The material of the Hollow A helix shaped devices is PTFE (Polytetrafluorethylene). Three PCDs were manufactured by the workshop of the department of Applied

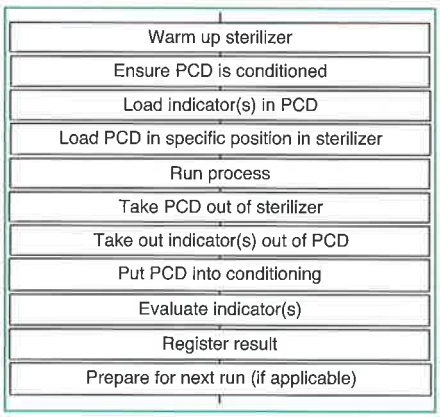

Fig. 2: Protocol used in the study of a hollow A PCD and standard test pack in both (small and large) steam sterilizers. In the morning the sterilizer is warmed up with a process with a sterilization phase of 30 minutes. Next an Air Leakage Test [12] is performed. Next the test cycle is verified. Between subsequent test runs, the temperature and the test cycle are verified. In case deviations from the programmed cycle would appear corrective actions will be taken. In the block «Load indicators(s)» indicator(s) are mentioned in plural because in a standard towel pack multiple temperature sensors have to be used [8]. Hollow A PCDs were always used solely in a process. With «warm up sterilizer» is meant that it had to be verified whether the sterilizer was ready for testing (warmed up and a verified test process) before loading a PCD and starting a test cycle.

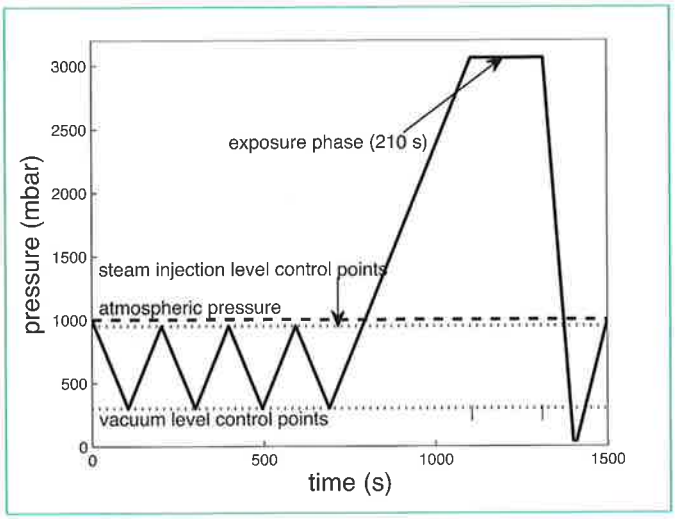

Fig. 3: Schematic representation of a B1 test cycle [8] used for testing. Before starting the exposure phase, the initially present air in the sterilizer chamber must be replaced by steam. In the test process four evacuations are used. Each evacuation is followed by steam injection. The lower dotted line indicates the level of the Vacuum Control Points (VCPs). In the presented process the VCPs are 300 mbar. In the tests only the vacuum level of the VCPs was varied. All four VCPs were set to the same vacuum level. The higher dotted line indicates the level to which the pressure is raised by in-jection of steam, 950 mbar. The dashed line represents the environmental pressure. Pressure increase and decrease was 400 mbar/minute in all cycles prior to the exposure phase. After reaching the aimed exposure temperature 134.2 °C (3050 mbar) this situation is maintained for for 210 s. After the exposure phase, the pressure is decreased to 30 mbar and then brought to atmospheric pressure again using filtered air.

Physics of the University of Technology of Eindhoven (the Netherlands). Measurement of the dimension of the devices showed that the specifications as specified for RRS device were met.

Before use the PCDs were conditioned. Lab conditions were a constant temperature of 23 °C and a Relative Humidity (RH) of 30 %. Conditioning of Hollow A PCDs was conducted by connecting the open end of the lumen to a vacuum system. Before connecting to the vacuum system, the cap of the receptacle was unscrewed so the environmental lab air was sucked through the receptacle via the lumen into the vacuum system. With this method the PCD was cooled down to 23 °C and the humidity in the cavities was reduced to 30 % RH within 15 minutes. Because three identical helix shaped devices were used sequentially the shortest time of conditioning corresponded to 2 processes. Each process with preparation took more than 15 minutes. Shortly before use the hollow A PCD was loaded with a Chemical Indicator (CI) and positioned in the center of the sterilizer, oriented such that the level of the capsule body was above the open end of the tube to allow free drainage (as in figure 1).

The used CIs were from the company Albert Browne International Ltd (Leicester, UK). Storage of the CIs was at 23 °C and 50 % RH. On the indicator a strip of 34 mm ink is printed. The color of this strip turns from yellow to blue when exposed to steam sterilization conditions. A complete coloration is established if the indicator is exposed for 3.5 minutes (210 s) to saturated steam at 134 °C. If these conditions are not established or not maintained long enough the ink strip would only partly change color or not change color at all.

Immediately after a process was ended the PCD was taken out of the sterilizer. The CI was removed out of the PCD and the length of coloration was measured and registered. The region that changed color was normalized by dividing it by the length of the strip. This yields to values between 0 (no coloration) and 1 (full coloration). After the registration, the hollow A PCD was connected to the vacuum system again.

During composition of the standard towel pack temperature sensors were placed at the specified positions in the test pack [8]. Sheets used to compose standard towel packs must have a Relative Humidity (RH) between the 40 and 60 % and have a temperature between 20 and 30 °C. This was established by ventilating the sheets in the laboratory. The relative humidity in the package was verified with RH measurements in the towel pack (Rotrinic, Type Hygromer S1, Ettlingen, Germany) and fulfilled the requirements.

Results

In the small sterilizer the CIs showed no coloration with VCPs of 400 mbar (figure 4) and higher. With VCPs of 320 mbar all tested CIs showed a complete coloration. With VCPs between 320 and 400 mbar no consistent results were found. With similar tests in the large sterilizer no coloration of the CIs was found at 400 mbar and higher, as well. Upon decreasing the VCP in the large sterilizer, the first partly coloration was found with VCPs of 370 mbar (figure 5). Between 320 and 380 mbar no consistent results were found. With VCPs of 300 mbar and lower all CIs changed color completely and reproducible, whereas above 400 mbar no CI showed any coloration.

In the process with the lowest VCPs (300 mbar) all CIs in the hollow A PCD gave a full color change in both sterilizers (table 1). This process was used for 10 times with a standard test pack in the large (342 l) sterilizer. The measured temperature depressions ($T_c - T_p$) were always time above 75 K. Obviously, these values are far above the criteria $T_c - T_p < 2$ K and explicitly show that this process is a fail process. To find reproducible pass results with the towel pack ($T_c - T_p < 2$ K) the VCPs had to be lowered to 50 mbar [8]. Compared to the first series consistent passes with the hollow A PCD in the small and large sterilizer this is a reduction of about a factor of 5 (table 1). To obtain a series of 10 consistent fails with the towel pack the VCPs had to be elevated to only 130 mbar. This value is about a factor of 2.3 (300 mbar/130 mbar) lower than the VCPs yielding consistent fails of the hollow A PCDs.

Discussion

Many modern surgical instruments contain narrow channels. In steam penetration sterilization a conventional towel pack may not be representative for steam penetration in the narrow channels of these instruments. Therefore a steam penetration test with narrow channels may have an additional value. In current standards [10, 11] such PCDs are proposed but are topic of discussion [13, 14]. To end this discussion conclusive data has to be made available. The ISO TC 198 WG 6 decided to perform a Round Robin Study (RRS) using a reference device with stricter defined dimensions than the current reference devices defined in standards. Unfortunately, this data is not yet available in the public domain.

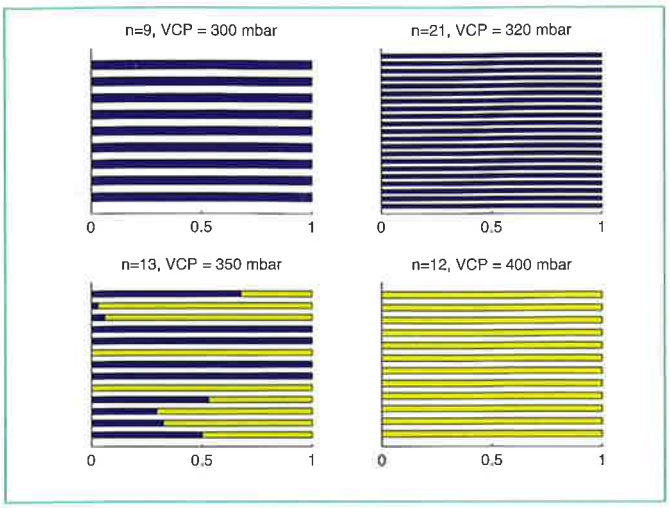

Fig. 4: CI results obtained with the small sterilizer (11 l) and the hollow A helix shaped PCDs. The «n» in the title of each bar histogram gives the number of tests performed and the «VCP» value gives the Vacuum Control Point depths in the test process (figure 3). A process with VCP of 300 and 320 mbar showed consistent passes. A VCP of 400 mbar shows consistent fails. All tests between 320 and 400 mbar show inconsistent results, e. g., VCP = 350 mbar.

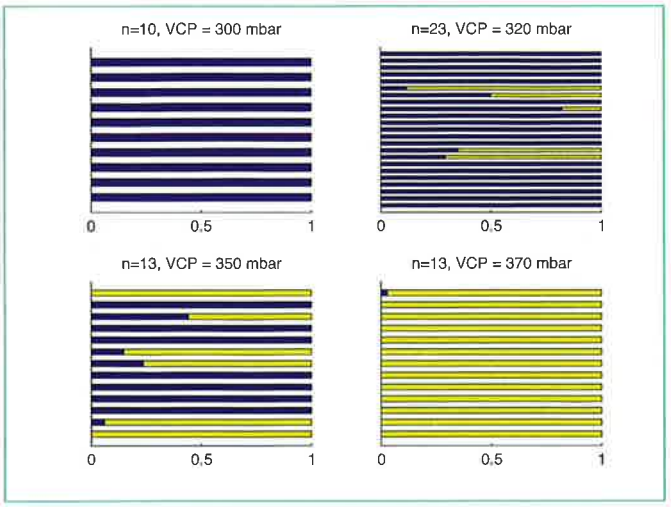

Fig. 5: CI results obtained with the large sterilizer (342 l) and the hollow A helix shaped PCDs. The «n» in the title of each bar histogram gives the number of tests performed and the «VCP» value gives the Vacuum Control Point depths in the test process (figure 3). Processes with a VCP of 300 mbar show a consistent pass. Processes with VPCs between 320 to 360 mbar showed inconsistent passes, e. g., process with a VCPs of 320 and 350 mbar. A minor in consistent was observed with a VCP of 370 mbar. Consistent fails were observed with a VCP of 380 mbar and higher.

It is likely that when the Round Robin Study (RRS) gives satisfactory results the characteristics of the materials used in the RRS will be specified in the standards. This narrowed down the choice of the materials for the hollow A PCD and CIs in the present study. The materials are identical to those specified and used in the RRS of the ISO TC 198 WG. Only the 40 % RH conditions of the protocol were not appreciated because a RH of 30 % is a realistic value in Central Sterile Supply Departments and other locations where steam penetration tests are performed. A lower RH may imply less initial moist in the CI, which may make the pass result more difficult but comes closer to the actual situation of use.

All results with a reference helix and CI show a full color change in the B1 test cycle [8] with a VCP of 300 mbar. These results must be interpreted as pass results. In the same process in a 342 l chamber, the standard towel pack test [8, 12] shows fails ($T_c - T_p \geq 75$ K instead of 2 K or less). Also huge differences were found between the levels of the VCP to obtain consistent passes and fails for the hollow A PCD and the towel pack, respectively (≤ 250 mbar in both sterilizers, table 1). Because standards define minimum requirements it must be concluded that the used reference PCD is not suitable as steam penetration tests for instruments with narrow channels. The fail is so large and conclusive (over a factor of 37 for temperature and over 250 mbar for the VCPs) that running other tests to check compliance with the standard [8] and initial RH conditions of PCD and CIs would be superfluous. These results also imply that PCDs which are tested against this reference hollow A PCD or the less strict PCD presently in the standards [11] are also not usable as steam penetration tests for instruments with narrow channels.

It might be argued that towel packs have different characteristics for steam penetration than narrow channels. On the other hand, because the number of medical devices with narrow channels is growing, a test for steam penetration in these devices would be very helpful, if not necessary.

Table 1: Summary of results. «Helix» stands for the helix shaped Process Challenge Device (figure 1). «B&D» stands for Bowie and Dick steam penetration test with the standard towel pack as defined in standards [7, 12].

Sterilizer	PCD	VU (mbar)	n_{passes}/n_{tests}	Pass results %	Results
Small	Helix	300	9/9	100	consistent pass
		320	21/21	100	consistent pass
		350	4/13	31	no consistency
		400	0/12	0	consistent fail
Large	Helix	300	10/10	100	consistent pass
		320	18/23	78	no consistency
		350	7/13	54	no consistency
		370	13/13	100	consistent fail
Large	B&D	50	10/10	100	consistent pass
		130	0/10	0	consistent fail
		300	0/10	0	consistent fail

However, it should be considered that a test device may look like a narrow channel in a medical device but differ strongly in characteristics. For example, the currently defined and used PCD could be described as a system of two volumes connected by a narrow channel. On one end of the channel the relatively large volume of the sterilizer is located and on the other end the relatively small volume of the receptacle. Compared to a channel with a homogeneous radius over its full length, as present in medical devices, PCD systems with communicating volumes will have different characteristics. It is therefore recommended to perform further studies on steam penetration in narrow lumen. In these studies known physical phenomena should be taken into account, as already suggested in literature [13]. As long as these phenomena are not quantified, tests based on a hollow A PCD should not be included in standards, because the results cannot be conclusive and, consequently, are of no help for users. Moreover, it can introduce unsafe situations. Therefore results of further studies should be used to define better requirements or reference devices for steam penetration tests representing narrow channels in medical devices.

Overall it has to be concluded that based on theoretical [13], experimental, and practical considerations, the reference hollow A PCD tested in this study and the hollow A PCD defined in the standards [10, 11] do not meet the current steam penetration requirement.

Therefore these reference devices, as well as PCDs tested against these devices, should not be used for steam penetration tests in daily practice. Until better references are available the current steam penetration requirements [7, 8] should be respected and used. ■

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