Drastic performance improvement of hand–operated sterilizers (at hardly any cost)

By only changing the operating procedures the performance of sterilization processes for porous loads in hand-operated sterilizers can be improved drastically.

In a great number of low-income countries, hand-operated sterilizers are commonly used for sterilization of medical supplies, including porous loads and hollow instruments. Due to the socio-economic situation in these countries the introduction of fully automatic sterilizers is not (yet) feasible. During a course on sterilization technology for hospital technicians at the Polytechnic in Mombasa, Kenya, some performance tests have been done with locally used sterilizers with standard test loads and loads as are common in the hospitals that were visited. The results for porous loads were alarming due to poor air-removal. Immediately a number of modifications in the processes were tested, based on an – in automatic sterilizers conventional - method of steam pulsing. This resulted in significant performance improvements and can be introduced at hardly any cost.

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Sterilization of medical supplies

In order to prevent transmission of disease it is necessary that medical supplies, which are used on open wounds or will be in touch with the inner fluids of the body, are free of any viable microorganisms: they have to be sterile. Before sterilization the items should be thoroughly cleaned to remove all dust and dirt. The most common agent used for sterilization of medical supplies is pressurized, high-temperature steam. Steam is a very effective killing agent, is not poisonous, penetrates the load very well and the process for making steam is easy to control. Sterilizers, which use steam as killing agent are referred to as steam sterilizers or autoclaves. In order to reach the high temperature needed for sterilization, the steam has to be pressurized. An autoclave basically consists of a strong vessel with a lid; the pressure inside the vessel can be accurately controlled. The load is inserted in the vessel - also referred to as the sterilizer chamber - and steam is admitted. For achieving sterile products, the load should be exposed to steam at a sufficiently high temperature for a sufficiently long time. The standard combinations of time and temperature for sterilization are: 134ºC for 3 minutes and 121ºC for 15 minutes. Which temperature is used depends on the type of load to be sterilized. At the start of a sterilization cycle air is inside the chamber. However in the case of hollow instruments and porous loads, such as textile, air is also inside the load. Air acts as an insulator for heat and seriously impedes the steam in reaching the surfaces of the goods to be sterilized. Therefore, in order to achieve sterilization, it is necessary that, before the actual sterilization phase starts, all air is removed, so that steam can penetrate and reach all exposed surfaces of the load. In hand-operated sterilizers the duration of the sterilization phase is usually extended to 15 and 30 minutes respectively in order to compensate for the poor air removal. However just extending the sterilization time proved not to be sufficient as pointed out in this article. In advanced, automatic sterilizers, this air removal is accomplished by evacuating the air with a vacuum pump, combined with steam pulsing, a technique where steam is removed and admitted in one or more consecutive pulses. In hand-operated autoclaves steam-pulsing is hardly used; however the tests as described in this article prove that the technique is very effective and can be easily performed without any additional cost. After taking the load out of the sterilizer it is necessary that it remains sterile until its actual use. This is why materials that are not immediately used should be sterilized inside a packaging. The package should allow air to pass out and steam to penetrate and of course it should prevent micro-organisms from reaching the actual load. Summarizing it can be said that sterile products are a result of a well packaged load in a well operating sterilizer running the right process.

Figure 1 Typical sterilization equipment as used in rural hospitals. The larger sterilizer is a double chamber model. The smaller one is a single chamber model of the pressure cooker type.

Most commonly used: Manually operated sterilizers

Most sterilizers installed in rural hospitals of low-income countries are hand-operated or semi-automatic sterilizers, where the process is controlled by manually operating of valves. Timing is usually done by a stopwatch or clock. Most common are the single chamber models, however also jacketed autoclaves are in use. Sterilizers which have a vacuum system are usually equipped with a vacuum system, based on a steam- or water ejector. The performance of such pumps as built in the autoclaves tested, is limited to a vacuum of approximately 0.25 Bar_{Abs}. The standard process being used for all types of loads is basically having the chamber reach the sterilization temperature, and keeping that temperature for 15-30 minutes (duration depending on the temperature), after which steam is released.

Performance-testing of currently-used processes

The materials and test equipment brought for the practical training during the course made it possible to do temperature measurements inside the load. These measurements give an impression of the performance of the sterilization processes currently used by the health services in the hospitals we visited during the course. Also at the school a number of performance tests could be done (See Fig. 2). Altogether a series of 11 tests were carried out. For this purpose a multimeter with a temperature probe was used. The accuracy of the measuring system at 130ºC was approx. ±4.5ºC. The thermo-couple connected to the multimeter was placed in the centre of the load and during the process the temperature was recorded each minute. The measurements resulted in a graph as shown in Fig. 3. Thus with very basic equipment we could get a good insight in the performance of the sterilizers. Many of the tests could be carried out within the scope of the practical training of the students. The main finding of the tests has been that the performance of the sterilization processes for textile packs is definitely not meeting the required conditions for attaining sterility due to poor air-removal. This also applies to sterilizers with a vacuum system on which measurements were done (See Fig. 3). At the end of the sterilization phase inside the centre of

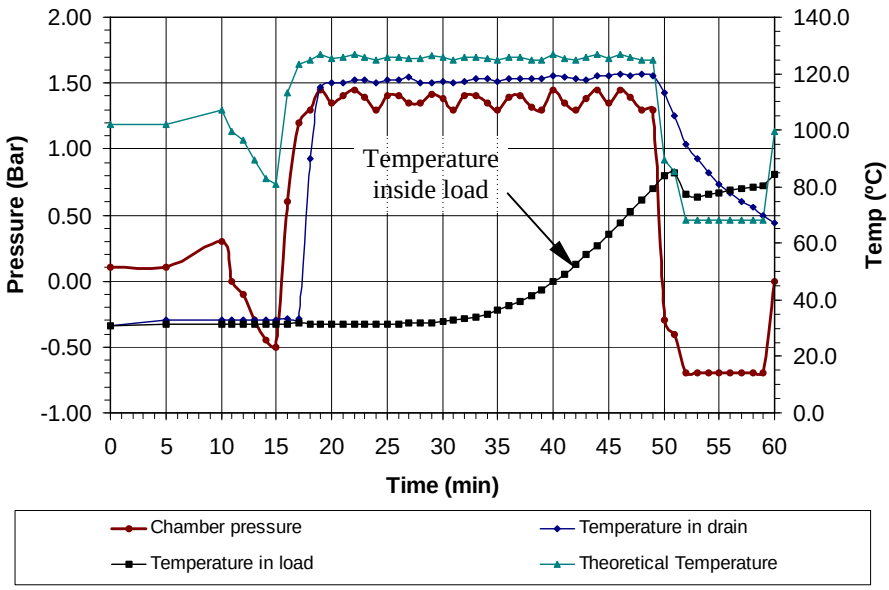

Figure 2 Recording of a sterilization cycle of a standard test pack of textile (Bowie and Dick test pack) during a process as normally performed in the sterilizer of one of the visited hospitals in Kenya. Main process parameters: 120ºC for 30 minutes, with pre and post vacuum. Due to the air trapped inside the pack, the temperature in the centre of the pack at the end of the 30 minute sterilization phase is only 80ºC. Compare this to the theoretical temperature which should be reached at the given pressure (approx. 125ºC).

textile packs, temperatures of only 70-80ºC were measured. This low temperature is definitely not sufficient for obtaining sterile goods and endangers the health of patients as well as hospital staff. These findings were a reason to start - already during the course - a series of tests in order to improve process performance.

General observations

Apart prom the poor performance of the sterilization processes the following observations were made during the visits to the sterilization departments:

- Cleaning of instruments is only done by hand; usually with a brush in water and soap.
- Poor loading practice of textile packs: Textile materials are often squeezed into drums. Also packs are put on top of each other in the sterilizer. These methods of loading make air removal extremely difficult, resulting in extra poor sterilizer performance.
- ***High-tech is trouble-tech.*** Advanced, automatic - and extremely expensive - sterilizers were found broken down for years due to lack of spare parts, unreliable electricity supply, problems with the steam supply or lacking know-how. Due to breakdowns, the machines quickly become a great financial burden, and drain the already so limited hospital budget. In the end usually the high-tech machines are abandoned and replaced by basic hand-operated or semi-automatic autoclaves.
- Packaging is usually done in cotton sheets or (Schimmelbusch) drums: Frequently these are damaged, old, worn or of poor quality.
- No or hardly any performance testing is done; only in some places sterilization tape is available.
- Training of staff in the sterilization department and of technicians is inadequate.
- The health services have very limited budgets available for re-equipping, maintenance and training.

Recommendations

Application of the following recommendations can result in considerable improvements. They all are related to operating, loading and performance testing of the sterilizer and can be implemented at hardly any cost:

- Improving air-removal
  For porous loads the air removal - and thus the performance of the sterilization processes - can be considerably improved by performing 2 or 3 steam pulses before actual sterilization starts (See Fig. 4). Steam pulsing, a technique where steam is released and admitted again by short pulses, is a well-

known method of stimulating air removal. It is a standard procedure in processes of automatic sterilizers for porous loads. It however is a procedure, apparently forgotten to be applied in the operation of hand-operated autoclaves. The steam pulses cause instability of the air held inside a pack and stimulate it to be driven out. The pulses can be easily performed by opening and closing the appropriate valve(s) of the sterilizer. Tests showed that the steepness of the pressure drop greatly influences the effectiveness of the steam pulse: the quicker the pressure drop, the more effective is the air-removal.

- Consider proper loading
  - Limit the size of textile packs
  - Keep spaces between individual packs. This can be accomplished by using containers of correct type or using perforated shelves inside the sterilizing chamber.
  - Don't squeeze textile materials in containers; a hand should be able to slide freely between sheets.
- Carry out adequate performance tests

  By technicians:
  - Standard steam penetration test (known as the *Bowie & Dick test*)
  - Validation of processes with the help of a single or double channel thermometer with a thermo-couple, allowing temperature measurements inside the load. The test results should be recorded. Record the temperature, pressure and time at each minute interval and evaluate the results. Recording can be done by hand. The recordings of an approved (validated) process can be used as a reference for sterilizer operators.

  By operators:
  - When using a validated process, performance testing for the operator can be limited to recording temperature and pressure throughout the sterilization cycle and verifying the results with the readings of a validated process.
  - For confirmation of the validity of processes, adequate chemical indicators can be used.

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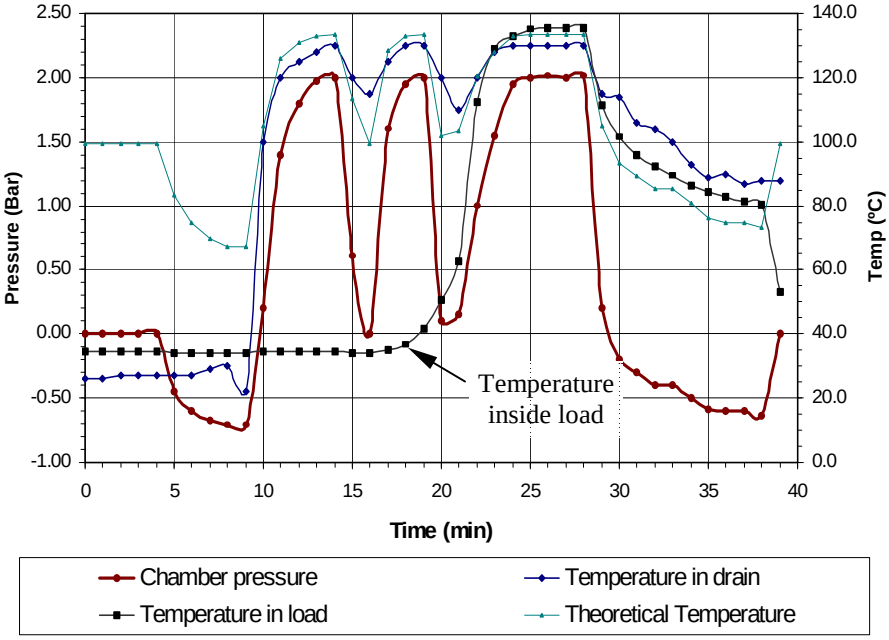

Figure 3 The effect of steam pulsing: Process recording of a standard Bowie and Dick test in a jacketed, horizontal sterilizer as shown in Fig. 2. Process profile: Prevacuum, 2 pulses down to 0 Bar, 3.5 minutes sterilization at 134ºC, post vacuum and air admission. By applying steam pulsing, air-removal is greatly improved. After 2 pulses the temperature inside the pack quickly reaches the required sterilization temperature.

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Summary

The performance of sterilization processes for hand-operated sterilizers can be improved drastically without great expenditures by steam pulsing before the sterilization phase. Also other steps in the supply of sterile goods can be improved considerably. However for formulating optimum recommendations, further research is needed. Organizations or institutes, interested to follow-up the further research are welcome to contact the author. If you have questions related to sterilization of medical supplies or if you have suggestions or experiences in this field which you want to share, you also are very much welcome to write to the author.

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