ÖGSV
Österreichische Gesellschaft für Sterilgutversorgung

ÖGHMP
Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin

Position paper of the Austrian Society for Sterile Supply (ÖGSV) and the Austrian Society for Hygiene, Microbiology and Preventive Medicine (ÖGHMP) on the current situation regarding low-temperature sterilisation with hydrogen peroxide (vH_2O_2 sterilisation) in Austria

Not least due to the increasingly widespread use of surgical robotics, the question of vH_2O_2 sterilisation methods for reusable critical medical devices is an increasingly discussed topic.

In 2018, the ÖGSV Technical Committee on Testing had already expressed considerable concerns in a corresponding statement regarding the effectiveness of vH_2O_2 sterilisation processes in terms of patient safety and referred to the statement of the then Ministry of Health (reference number: BMGF-20560/0039-III/2/2006).

In the meantime, a European draft standard on vH_2O_2 sterilisers (prEN17180) and an international standard for the validation of vH_2O_2 sterilisation processes has been published (ISO 22441). The prEN 17180 standardisation document is still in the draft stage due to objections from several countries in the CEN committee. The adoption of ISO 22441 as an Austrian or European standard was rejected by the Austrian standardisation committee due to the following weaknesses, which are documented in publications:

- Limitation of sterilisation reliability due to organic and inorganic contamination (e.g. macroscopically imperceptible protein residues or salts) (1-4). (Note: For high sterilisation reliability, this circumstance would require that – apart from the highest level of validated cleaning, which must not leave any residues on the medical device – the cleaned medical devices must no longer be touched with bare hands.)
- The material of the medical device can have a significant impact on the effectiveness of the process. (5) In some cases, there is a lack of 'positive lists' from device manufacturers and confirmations from medical device manufacturers that the medical device in question can be sterilised using the specific H2O2 process.
- The use of Lumina for vH_2O_2 sterilisation of medical devices is generally considered problematic and is usually excluded by device manufacturers, or the length and diameter of Lumina in such medical devices are limited.
- The standard specified in the ISO standard for the bioindicators to be used (ISO/CD 11138-6) is still in the draft stage. To date, there is no reliable data to prove that the test organism Geobacillus stearothermophilus, which has been designated for use to date, can be considered the most resistant microorganism to vH_2O_2 processes. It is more likely that catalase-forming microorganisms (e.g. staphylococci) are more resistant to the process. From this perspective, the 'offer' to validate the sterilisation process with bioindicators that use Geobacillus stearothermophilus in accordance with ISO/AWI 11138-6 appears highly questionable.

• Parametric approval does not appear to be possible in the case of vH_2O_2 sterilisation, as this requires the verifiability of all relevant process parameters. It has not yet been clearly established whether and how the relevant active parameters of vH_2O_2 treatment can be reliably monitored and controlled under practical conditions.

The adoption of ISO 22441 as a European standard was also rejected by other member states, which means that neither prEN 17180 nor ISO 22441 has yet come into force as a European (and thus Austrian) standard.

There is still a lack of independent publications/studies that would dispel the concerns mentioned above. Similarly, manufacturers of vH_2O_2 sterilisers have not yet provided any conclusive data or studies that would dispel these concerns.

Critical voices have also been raised in Switzerland and France, as presented in three papers at the symposium of the Swiss Society for Sterile Supply in June 2024 (6-8).

- It has been pointed out that, in addition to the degree of cleanliness, the total surface area of the medical devices to be sterilised is also crucial to the effectiveness of the process, as relatively small amounts of H_2O_2 are injected. Therefore, batches should be assembled according to the surface area to be sterilised, which raises questions about practicability due to a lack of data on this subject (6).
- The process is not continuous; temperature and pressure change during the course of the process depending on the type and material of the load, which also changes the conditions for condensation of the effective agent. This means that validation using the 'half-cycle method' is not possible or effective in most cases.
- The 'full cycle method', on the other hand, requires the microbiological inactivation capacity to be calculated on the basis of an indirect or direct measurement of the H2O2 concentration in the load (7).
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Sterilisation with vH_2O_2 is a complex process in which the following factors (in addition to those already mentioned) must be taken into account:

- the composition of the reference batch, which must correspond to the operating conditions, and its weight;
- the type and composition of the medical devices;
- compliance with a 'positive list' provided by the manufacturers;
- the results of physical measurements and the different cycle types (8).

For successful sterilisation with vH_2O_2, the following conditions must also be observed, which can be difficult and/or costly under practical conditions:

- The medical devices must be completely dry for the procedure.
- The packaging must not contain any cellulose, as this absorbs H2O2. Special packaging, e.g. made of Tyvek®, is therefore required.

In this context, it is also worth noting the running costs associated with the routine use of vH_2O_2 sterilisers, which, according to a presentation given at the WFHSS Congress 2022, can be significantly higher than those associated with low-temperature steam formaldehyde or steam sterilisation processes (9).

If 'reliable' validation of vH_2O_2 sterilisation methods appears possible in the future, it would be more complex and therefore more cost-intensive than that for steam sterilisation methods.

From the perspective of professional associations, it is also particularly problematic that for some medical devices, their manufacturers define vH_2O_2 sterilisation as the only permissible sterilisation method.

Summary

In summary, it can be said that the low-temperature sterilisation process using vaporised hydrogen peroxide (vH_2O_2 sterilisation) is still associated with a great deal of uncertainty and therefore should not be considered a substitute for steam sterilisation under any circumstances. Whether and for which types of medical devices vH_2O_2 sterilisation can be recommended requires the resolution of the open questions outlined above and cannot be decided at present.

Therefore, the principle that all medical devices that can be steam sterilised must also be sterilised in this way still applies. Medical devices for which vH_2O_2 sterilisation is defined by the manufacturer as the only permissible sterilisation method require particularly critical consideration with regard to possible alternatives.

Taking into account the unresolved issues, the ÖGSV and ÖGHMP currently see no basis for standardised validation of vH_2O_2 sterilisation processes.

The ÖGSV Technical Committee on Testing and the ÖGHMP Executive Board therefore strongly advise against using vH_2O_2 sterilisers for the sterilisation of critical medical devices until the above concerns have been resolved.

Literature

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