Does storage method and duration have an impact on sterility when using self-seal autoclave bags to sterilise surgical instrumentation?

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Introduction

There is currently no veterinary research to support an optimal storage duration and method of sterile surgical instrumentation (SI) when using self-seal autoclave bags (SSABs) in clinical practice, although aspects of research from human healthcare is transferable. Multiple pieces of research in human healthcare have demonstrated the ability of sterilisation packaging materials in maintaining the integrity and sterility for several months to years post sterilisation (Bhumisirikul *et al*., 2000; Bhumisirikul *et al*., 2003; Puangsa-Ard *et al*., 2018; Klumdeth *et al*., 2020). Existing research could be used as a guide, but due to multiple limitations and the differing scientific field and medical environment, many findings cannot be extrapolated to clinical practice until further veterinary research is conducted. Research on storage duration and method of the most frequently used sterilisation packaging material in the veterinary practice (SSABs) is lacking. Furthermore, optimal storage method in human medicine is inconclusive.

The aims of this Masters degree research were to determine an ideal storage duration and method of single SI, packaged in SSABs and sterilised via autoclave, and to determine the current practice of sterilisation, storage methods and durations when using SSABs in practice. Furthermore, research on this topic was required as the use of SSABs should be considered in line with the Vet Sustain Greener Veterinary Practice Checklist to ensure practices are adhering to sustainability guidance.

Figure 1 . Visual assessment of blade holders in NB (NB in left jar is clear, NB in right jar is cloudy/increased turbidity indicating contamination).

Methods

This mixed methods study consisted of an online questionnaire to investigate the current procedures of autoclave sterilisation in the veterinary practice. Alongside this, a non-randomised control study was conducted to assess the sterility of 60 single instruments (blade holders), packaged in SSABs and sterilised via autoclave to determine an ideal storage duration and method. SI was sterilised and stored for one, three and six months, in open (on open shelving) and closed (in a closed box) environments prior to transfer into individual jars containing sterile nutrient broth (NB) and subsequent incubation (Figure 1). Following a 48-hour incubation at 37.5 degrees Celsius, samples of NB were analysed in a laboratory using a spectrophotometer to assess for microbial contamination. A light wavelength of 600 nanometres (OD600) was used to determine the turbidity of the samples. Samples with an OD600 of ≤0.099 were deemed sterile. Samples with an OD600 of ≥0.100 were deemed contaminated as this indicates increased turbidity, most likely associated with contamination. Visual turbidity (Figure 1) and odour assessment of the NB was also conducted with malodourous samples being indicative of contamination. Ethical approval was granted and piloting was conducted prior to beginning the study. Descriptive and inferential statistics were conducted on both data sets. A P value of ≤0.05 was set as the level of statistical significance.

It was predicted that results would be similar to those in existing human literature which demonstrated the ability of packaging materials in maintaining sterility for long durations.

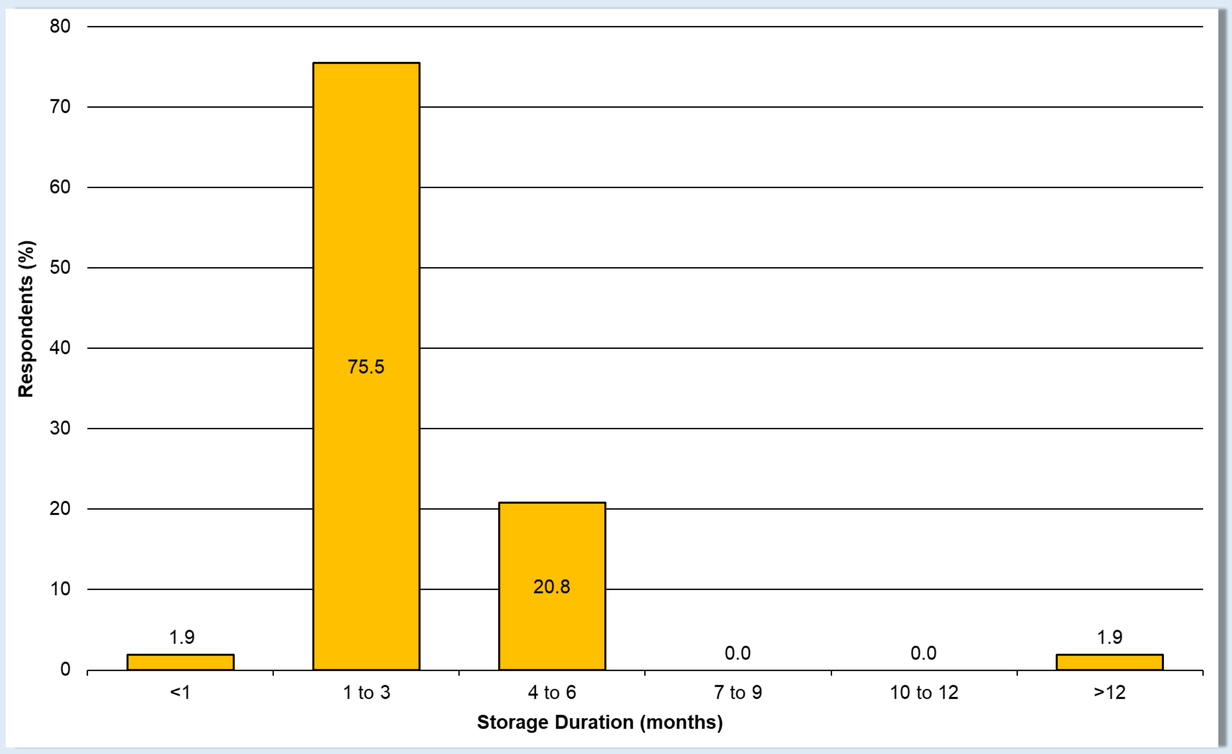

Figure 2. Maximum storage durations of single instruments prior to rebagging.

Results

- A total of 59 participants took part in the questionnaire. Single bagging was the most selected method for packaging and sterilising single SI as selected by 89.8% (n=53) of participants. The most common storage duration of single bagged SI was between one and three months (n=40, 75.5%) prior to reprocessing, followed by four to six months (n=11, 20.8%) (Figure 2).
- A statistically significant difference was not identified between the spectrophotometer values of the open and closed groups for all durations (one P=0.617, three P=0.918, six P=0.987).
- An 8.5% contamination rate was observed (n=5/59) with 5% (n=1) in group one, 10.5% (n=2) in group three and 10% (n=2) in group six. Furthermore, the OD600 values of the contaminated samples were significantly higher than those of the sterile samples indicating an increase in turbidity as a result of microbial contamination (P=<0.001).
- A statistically significant difference was identified between the spectrophotometer values of all storage duration groups (open and closed combined) (P=<0.001) but due to the small sample size and the distribution of the contaminated samples across the groups, the clinical significance of this result is questionable.

Discussion, Conclusion and Suggestions for Further Research

Research shows consistent findings with those in existing human literature suggesting longer storage durations do not impact the sterility of SI as 54 samples were sterile at the end of storage. Durations examined in the literature are significantly longer than those used in current veterinary practice which implies veterinary professionals are adopting a cautious approach to infection control procedures. If practices adhere to current evidence, savings could possibly be achieved in supply and labour costs without impacting patient care, in addition to improving sustainability performance. No significant difference was identified between the OD600 values of the open and closed groups across each storage duration. This suggests a superior storage method to maintain sterility of SI does not exist and either open or closed could be used for effective storage up to six months in undisturbed conditions. A suggestion for the current 8.5% contamination rate is inadvertent contamination during transfer of the instruments from the SSABs into the NB jars, as opposed to package deterioration.

A prevention is better than cure approach is often adopted in practice and as sterilisation is a major factor in the prevention of disease transmission, further research would be beneficial. Suggestions include single versus double bagging of SI, the effect of frequent handling and events on the sterility of stored SI, the impact of further storage durations in a clinical environment and whether early loss of sterility is associated with the weight and/or size of the SI contained in the SSAB.

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