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ORIGINAL RESEARCH: PILOT STUDY

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Glass particle contamination threat in nursing practice: A pilot study

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Abstract

Aim: The aim of this study was to determine the level of glass particle contamination from medical ampoules during breakage in nursing practice and their removal by filtration.

Design: Glass medical ampoules were broken-open as instructed and contamination was assessed microscopically.

Methods: Three types of medial ampoules (A, B, C) were used. Dispensation of contents was carried out using 21 or 22 G needles, with and without syringe-filters. Particles were determined by light microscopy. This study was conducted between April 2018 and January 2020.

Results: Glass particles of 0.94–90.70 μm were detected in 94% of all samples. There were 48, 162 and 201 glass particles in groups, A, B and C, respectively. Filtration had no effect in group A but was effective up to 85% in the other groups.

Conclusion: This study confirms that ampoule contents are contaminated with glass particles during the opening procedure, which varies with make and content. Syringe-filter use can be up to 85% effective in their removal.

Impact: Use of syringe-filter can decrease glass particle contamination up to 85%. Innovative nursing studies are needed to minimize or completely avoid particule contamination.

KEYWORDS
ampoule, contamination, glass particle, nurse, nursing practice

1 | AIM

Glass ampoule form drugs are generally prepared for treatment by nurses. If macro glass particles are evident, contents are discarded. However, microscopic particle contamination does occur and cannot be visually assessed (Lee et al., 2011; Preston & Hegadoren, 2004; Sabon et al., 1989), which poses a serious health threat. It is reported that 15–419 glass particles that can be up to 1 mm in size can form and mix with contents of each ampoule during breakage (Joo et al., 2016). Glass particles of 10–12 μm in size can often stay stuck in pulmonary capillaries and can trigger granuloma formation. Smaller particles can reach the lymph nodes of internal organs, which can lead to nodular cirrhosis due to silicosis-induced fibrosis (Preston & Hegadoren, 2004; Sabon et al., 1989). Therefore, it is important to reduce/remove glass particles in nursing practice.

The aim of this study was to determine the level of glass particle contamination from medical ampoules during breakage in nursing practice and the efficiency of particle removal by syringe-filter use.

2 | DESIGN

Three types of ampoules with different drugs (A, B, C) were studied. Each type was divided into subgroups as described below: Ampoule

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contents were withdrawn with 21 and 22 G needles. The dispensation was made with (subgroups b and d) or without filter (subgroups a and c), respectively.

3 | METHODS

This study was conducted between April 2018 and January 2020. The sample size was ascertained using GPower Software (with a power of 0.95, and an effect size of 0.40). A total of 60 brown glass ampoules with a volume of two ml were used. The form of the ampoules represents some of the most frequently used in clinics. The colour was to aid in microscopic evaluation. The numbers and contents were selected to allow meaningful analysis and to determine effects of contents on particle generation. Three different make and contents were selected to determine if and how much effect they had on particle generation. Choice of brown colour was enable for easier visual identification of glass particles. 5 ml sterile syringes with 21 and 22 G needles were used for content withdrawal and transferred to a 96-well sterile cell culture plate (32096; SPL Life Sciences). 0.22 µm syringe-filters were used for filtration (SLGV033RS; Merck Millipore Ltd. Tullagreen, Carrigtwohill, Co.).

The necks of the ampoules were wiped with alcohol and broken-open manually by an academic nurse. Transfer of contents to the plate, five drops/sample/well, was carried out as described above. The wells were examined using an inverted light microscope with camera (Leica DMI1, MC170HD; LAS Core). After determination of two-dimensional measurements of the particles, they were photographed, and the data were saved.

The data were analysed using the SPSS 21 program. Data were evaluated by calculating the mean, standard deviation, frequency distribution, and by applying the Kruskal–Wallis and Bonferroni-corrected Mann–Whitney *U*-test.

4 | RESULTS

Sixty ampoules were used in the study. 428 images and related microphotographic measurements from 120 samples were taken. Surfaces with sharp edges and light reflections of glass particles were clearly visible in the images. Their morphologies were compatible with those reported in the literature.

Glass particles in groups A, B and C (48, 162 and 201, respectively) ranging in size from 0.94 to 90.70 µm were detected in 94% of the samples (Figure 1). While filtration failed to reduce the number of glass particles in Group A, it provided 51%–65% particle retardation in group B and 85% in group C.

The particle sizes of the subgroups of every group were statistically compared. A statistically significant difference was found between subgroups c and d of group A ($p < 0.001$) only, with the former having larger particles. There was no significant difference between the subgroups of the other groups.

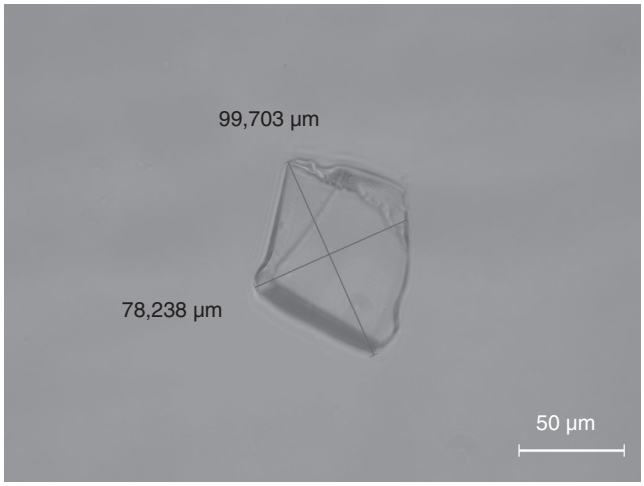

FIGURE 1 An example image from subgroup c

The number of glass particles detected in this study was less than those reported in the literature. It is apparent that more particles contaminate contents than detected as reported before (Timmons et al., 2017). Use of 6%–17% of the ampoule contents, not centrifugation of the ampoule before sampling and exclusion of particles that were <5 µm may partially account for this. The morphology of the glass particles detected in this study is consistent with the images reported in the literature (Lee et al., 2011; Preston & Hegadoren, 2004).

It was previously reported that filter-needle was effective in removing glass particles >200 µm (Sabon et al., 1989). In this study, it was shown that the syringe-filter removes glass particles over 90 µm. Since glass particles are hard with sharp surfaces, some larger ones could conceivably pass by lacerating the filter membrane. In addition, the content and make of glass can have an impact on the effect of removal by filtration as shown in this study. The constituents of the glass ampoule and their proportions can affect fracture flexibility, and thus, particle generation during opening. Even though the production of glass ampoules is standard, there may be some structural differences. No published research has been found in this respect. Thus, there is a need to follow innovations and establish a standard procedure in this regard.

5 | CONCLUSION

This study confirms that ampoule contents are contaminated with glass particles during opening, which should raise awareness among nurses and physicians. Particle generation is influenced by make and content of the ampoule. Syringe-filter use can be partially effective in their removal, which is recommended in all settings. Complete removal of particles and prevention of their generation require further studies.

6 | IMPACT

Use of syringe-filter can decrease glass particle contamination up to 85%. Innovative nursing studies are needed to minimize or

completely avoid particle contamination, and issue that concerns health sciences in general.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/jan.14847.

DATA AVAILABILITY STATEMENT

Author elects to not share data.

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