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Addressing Glass Contamination in Radiology: What Can We Do to Minimize Its Impact?

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Abstract

Introduction There is a risk of glass contamination with the use of single-dose glass ampoules. Complications of injection include infection and granuloma formation and this is widely described in anesthetic literature. To date, there is no data on the effect of different ampoule opening methods on the degree of glass contamination.

Purpose This article explores different ampoule opening methods and determines if any method is superior to the others with respect to glass contamination frequency. This article also increases awareness of glass contamination and its potential complications in the radiology community.

Methods A controlled trial was undertaken with 15 glass ampoules filled with normal saline, divided into three groups. The ampoules in each of the group were opened via each method: freehand, ampoule breaker, and ampoule opener. The solution was aspirated with an 18-gauge drawing-up needle, which was centrifuged and decantered to be placed onto slides and inspected under light microscopy to assess the glass contaminants.

Results Between each cohort, the freehand opening provided the least number of glass particles with 42, followed by the ampoule breaker and snapper. The greatest size of glass contamination was seen from the ampoule snapper at 300 µm, while the lowest average particle size was seen from the ampoule breaker.

Conclusion The study confirmed presence of glass contamination in all three methods. Freehand opening minimized the number of particulates, while the ampoule breaker minimized the average particulate size. The ampoule snapper produced larger glass particulates in the trials and was deemed the least effective method.

Keywords
- glass ampoules
- glass contaminates
- ampoule breaker

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Introduction

Many therapeutic drugs are stored in single-dose glass ampoules. In the process of opening these ampules, glass particulates can be released and can contaminate the injectate.[1] Animal studies have demonstrated that continual intravenous administration of glass particles over time has been shown to cause pulmonary emboli and granuloma formation in pulmonary, hepatic, splenic, renal, and intestinal distribution.[1] Complications at intramuscular injection sites, including pain, bleeding, or hematoma formation, acute inflammatory induration, and formation of transient nodules in humans have all been observed.[2] There is also a theoretically increased risk of infection with glass contamination.[3]

In a case report of intra-articular injection of the knee joint, a 1.6-cm glass foreign body was found in an extracapsular location on arthroscopy.[4] The late and episodic migration of the glass piece into the joint from its extracapsular location produced acute pain and locking of the joint for the patient. Glass particulate size has been shown to vary from 5 to 85 µm.[2] This is particularly relevant to radiology, given the extensive use of therapeutic procedures utilizing particulate steroids, such as betamethasone acetate, of which the size varies between 5 and 8 µm.[5] The frequency of glass contamination is also of note, whereby a study found 449 of 672 glass ampoules to contain glass particles,[6] further compounding the incidence of this issue.

The glass contamination can be negated in certain situations, with the use of filtered needles which can remove particulates that are greater than 5 µm.[7] However, this is not applicable in musculoskeletal injections, as the size of particulate steroids is larger than 5 µm and the literature recommends the use of particulate steroids for musculoskeletal injections over nonparticulate steroids,[5] given their therapeutic advantage. Therefore, glass particulate would not be viably removed from a filtered needle without preserving the particulate steroids.

The opening of glass ampoules in clinical practice is often achieved by merely using the freehand technique. As an alternative to freehand opening, there are different commercially available ways of opening glass ampoules. These alternative methods aim to reduce the risk of cuts and bleeding for the user, as well as minimize spillage of the injectate.[8] The ampoule opener helps by enclosing the tip of the glass ampoule and holding it in place, so that the ampoule snaps at the neck. The ampoule breaker, on the other hand, has different-sized slots where the neck of the ampoule can be placed in and snapped at this point. There is an absence of data in the literature as to which method results in the least frequency and size of glass particulates. The aim of this study was to determine which of the above three methods, freehand, ampoule opener, or breaker, has a better glass contamination profile.

Materials and Methods

Fifteen 1-mL glass ampoules filled with distilled water were used to compare the results of the different methods of breaking glass ampoules. This was subdivided into three different equal groups; those broken with an ampoule breaker, seen in ►**Fig. 1A**, ampoule snapper, seen in ►**Fig. 1B**, and the freehand technique. The solution from the opened vials was then aspirated using an 18-gauge drawing-up needle into a single 10-mL syringe and transferred into a 10-mL test tube which was then centrifuged and decanted using a micropipette. The decanted solution was then prepared in five slides per group, and examined under light microscopy.

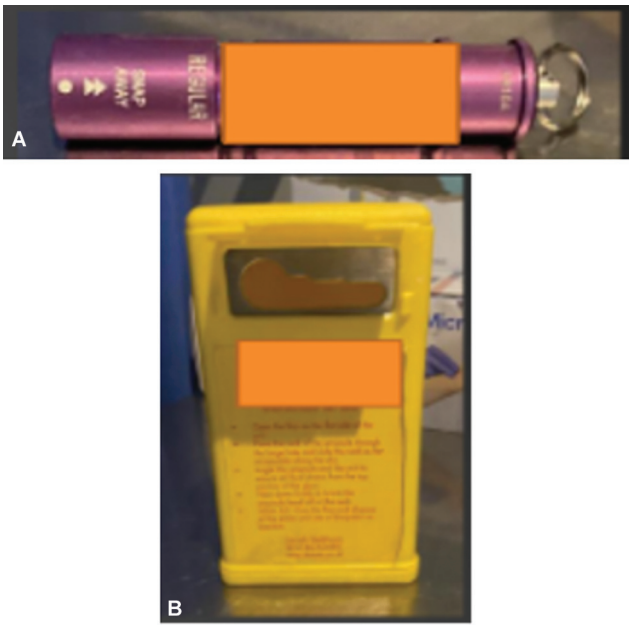

Fig. 1 (**A**) Ampoule opener. The tip of the ampoule is inserted into one end of the ampoule opener, which is then manually snapped open. (**B**) Ampoule breaker with different-sized slots to fit the neck of the glass ampoule. On snapping, the tip of the glass ampoule is then collected within the container.

Methodology

Through consultation with a microscopist, the provided slides were accompanied by glass scratching obtained from a diamond pen as the positive control, to determine the microscopic appearance of glass. Furthermore, a slide with only normal saline solution was prepared and used as a negative control. Once the ampoules were opened, the solution was aspirated with an 18-gauge drawing-up needle. This was then centrifuged down and aspirated again to be placed onto slides. Then, each slide from the three groups was examined under light microscopy with and without a polarized light filter, with ►**Fig. 2A** and **B** illustrating examples of 40× and 20× magnification, respectively. Any particle that was identified was photographed for analysis later. All photographs were analyzed by authors S.K. and W.Y.L. and assigned a certainty score, either positive for glass or most likely glass, and size using Olympus cellSens. Data was then collated between all the five slides in the same cohort to determine the total number of definite glass particles, the number of potential glass particles, range of particle size, total number of particles identified, and average particle size.

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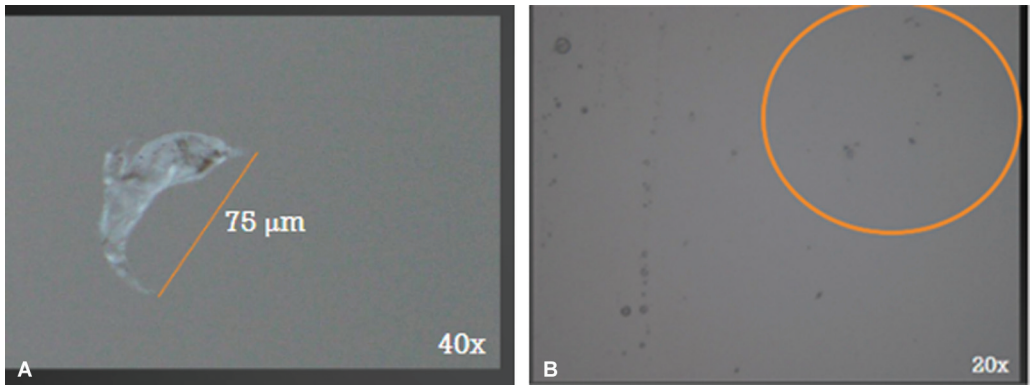

Fig. 2 (A) Example of glass contamination as seen using 40× magnification (length illustrated with orange line). (B) Example of glass contamination as seen using 20× magnification (evident in orange circle).

Results

The number and size of the particles from each group are as tabulated (►**Table 1**). Freehand opening produces the least number of glass contaminant (36) compared with ampoule breaker (42) and ampoule snapper (101). The group with the ampoule snapper also has the largest sized particle (300 µm) and thus the greatest range of particle sizes (20–300 µm); the smallest range being from freehand opening (10–110 µm). However, it can be noted that no particles below 20 µm were found from the ampoule snapper. Finally, the average size of particles was the least for the ampoule breaker (32 µm), as seen in ►**Table 1**, while the other two methods provided invariably greater sizes. ►**Fig. 3A** and **B** illustrate jagged edges of the opened vials with macroscopic glass visible for both the ampoule breaker and ampoule opener, whereas ►**Fig. 3C** shows no macroscopic glass for the freehand technique.

Discussion

From the data, the three methods of opening glass ampoules provided varied results in regard to the number and size of glass contaminants. The freehand opening method seems to yield less glass contamination and smaller-sized glass particles whereas the ampoule snapper group contains a higher number of glass contaminants, which are also of larger size. Clinically, this means that freehand opening would likely be more effective to use when patients require consistent doses of the injectate, reducing the amount of glass contamination. Each method led to the identification of particles that were not definitively determined as glass particles and were felt to be contaminant and thus a method for further interrogating these particles should be considered. When visually inspecting the vials, the site of the opening was observed to possess jagged edges. As the opening should be clean and have a smooth finish, this suggests that these methods may be

Table 1 The number and size of glass particles with respect to each opening method

Opening method	Positively glass	Probably glass	Range of particle size (µm)	Total number	Average size (µm)
Freehand	35	1	10–110	36	41
Ampoule breaker	40	2	10–148	42	32
Ampoule opener	100	1	20–300	101	53

Fig. 3 (A) Jagged edges of the ampoule after opening with the ampoule breaker. Macroscopic glass is noted to be present (orange arrow). (B) Edges of the ampoule after opening with the ampoule opener. Macroscopic glass is noted to be present (orange arrow). (C) Edges of the ampoule after opening with freehand. No evidence of macroscopic glass.

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inconsistent in opening the vitals in a safe way, thereby introducing the risk of glass contamination.

The number and range of particle size between freehand and ampoule breaker were similar and may not be significant. The ampoule snapper group had more frequent and larger glass particles, suggesting that using this opening method may present greater harm to the patient. However, because of the methodology of the study in which all five ampoules in each group were opened and drawn up into one single syringe, and thus it is unclear whether the glass contamination is indeed more prevalent in the ampoule snapper group, or whether the results were skewed by one of the five ampoules. In other words, the frequency of glass contamination from each ampoule has not been established in the study.

Until further study is performed to determine the safest method of opening glass ampoule, other methods could be undertaken to reduce the risk of glass contamination in glass ampoules. These include: allowing the injectate to sit for a while for the contaminate to sediment to the bottom of the vial, aspirating from the side rather than the bottom of the ampoule, or using a filtered needle where possible.[3] Several complementary methods of mitigating glass contamination, such as the use of a vacuum machine opener[9] and filtered drawing-up needles when clinically viable,[2] would also need to be considered as alternatives.[10,11]

The relevance of glass contamination in the opening of glass vials should be further established in the radiological community, given the potential risk of adverse events. For instance, it is routine practice now to use nonparticulate steroids for epidural injections to reduce the risk of brain or cord infacts.[10] This stems from the theory that particulates can lead to end-arteriole embolism in the event of intravascular injection. Given that particulate steroids range from 0.5 to 100 µm, one may argue that based on the size of glass contaminants in our study, glass embolism leading to inadvertent cord infarcts is a definite possibility.[11] There are certainly cases of cord infarction following nonparticulate epidural steroid injections,[12] which should force us to rethink other possible mechanism of injury and specifically, glass contamination and inadvertent glass embolism.

Limitations

As eluded to earlier, limitations from this pilot trial include combining the number of glass ampoules in each group rather than determining an average or frequency of glass contamination. The limited sample size of five ampules per trial reduces the strength of the data. This methodology was undertaken as there was initial uncertainty regarding how much glass contamination was expected. The results of the current study should incite further studies in individually testing ampoules to provide a more precise record of glass contamination per ampoule. Mechanical opening of the glass ampoules promotes invariable force and the degree of shattering between trials, and thus a more consistent approach should be undertaken to standardize such process. Furthermore, the utilization of electron microscopy would have elicited a more precise determination of glass particles and accurate measurement of their size.

Conclusion

This pilot study determined the efficacy of certain methods when opening glass ampoules, in order to minimize the incidence of glass particulates within the injectate. This provides the opportunity to extend this study with a larger sample size and a more accurate method of measuring glass contamination, such as electron microscopy, to further determine which method of opening is safer. Ultimately, the importance of mitigating glass contamination should be present within the radiological community, due to the common use of glass ampoules, and the rare but significant implications of glass contamination in subtherapeutic effects or undesirable complications should be effectively determined.

Ethical approval

Study is exempt from ethics review as there is no patient involvement.

Authors' Contributions

S.P.: Literature search, data analysis, statistical analysis, manuscript preparation, and manuscript editing.
S.K.: Concepts, design, definitions of intellectual content, experimental studies, and data acquisition.
S.Z.: Definitions of intellectual content and manuscript review.
W.Y.L.: Concepts, design, definitions of intellectual content, literature search, experimental studies, and data acquisition.

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Conflict of Interest

None declared.

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