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Humipak Validation

Kaumudi Kulkarni, M.S.

BACKGROUND

The importance of improving cleaning efficiency of patient used reusable surgical instruments is well established. Though it is recognized that contaminated surgical instruments be cleaned immediately after use, it is observed that this is not always practical. However, dried blood does represent a great challenge to cleaning of patient used instruments (ANSI/AAMI ST79:2010 7.5.2). Thus it is highly recommended that patient used instruments be kept moist until the cleaning process begins to avoid drying of debris (ASCRS, AORN: 2007- Recommended practices for cleaning and sterilizing intraocular surgical instruments). In addition, there is also a problem of biofilm formation especially in lumened instruments. To prevent its formation, cleaning should occur as soon as possible after instrument use (Integra, Jarit Endoscopic instruments). Humipak pouches (Westfield Medical Ltd) come as a solution here. They are manufactured from low linting, highly absorbent material sandwiched between two layers of a transparent film laminate. The transparent layers enable observation of the materials kept in the pouch. Water is added to the absorbent material and soiled instruments are kept in the pouch, which is then sealed. This creates a moisture retaining pouch and the instruments remain in a moist state until taken for cleaning. The humid atmosphere within the pouches prevents the drying of protein on instruments. This in turn facilitates an increased efficacy of cleaning the patient used surgical instruments by reducing the time, chemicals and energy required to clean dried instruments. A further benefit of such a product design is reduction in the reprocessing costs of contaminated instruments.

STUDY DESIGN

A study was designed to observe the optimum time the blood soils applied on surgical instruments retain their moisture in the Humipak. Two coagulating blood based soils namely Citrated Sheeps blood coagulated with calcium chloride (ISO/TS 15883-5:2005 M.7.2) and Coagulating Blood Soil (distributed by Healthmark Industries Co.) were used. These coagulating soils pose a tough challenge that closely mimics human blood soil remaining on patient used reusable medical instruments.

Commonly used reusable stainless steel medical instruments were soiled with these two soils. Different areas- for example tips, serrated edges, box locks of these instruments were soiled. The area for soiling and the amount of soil used for each application was variable and not kept uniform in order to closely correlate with the postoperative real life situations. After applying the soil on these instruments, they were soon placed in the pouch to which the suggested amount of water was added. The pouch was then sealed and placed for observation. The soiled instruments in the sealed pouch were observed after 30 min, 2 hr, 24 hr, 3 days and 5 days. These timelines correspond to the potential time the instruments could

be left while awaiting cleaning: including same-day, overnight, weekends as well as cases when soiled instruments are brought in from remote locations for proper reprocessing. Instruments painted with both the test soils, but left open in trays and not in Humipak were used as a control.

To simulate a worst case scenario recalcified Sheep's blood and Coagulating blood soil applied on stainless steel medical instruments and allowed to dry for 5 days at room temperature, were kept in Humipak and were then checked for rehydration of the dried soil.

To study moisture retention in soiled cannulated devices, lumens of suction tips were soiled with Coagulating blood soil. Cannulated and channeled medical devices often have organic residues trapped in their lumens and channels after patient use. If not cleaned soon after their use, this residue build up may dry and be a challenge to reprocess. So the suction tips soiled with the Coagulating Soil were kept in the Humipak for 2 hrs, 4 hrs, 2 days and 3 days, to see if the soil in their lumen remains moist. Their respective controls were left in open air at room temperature. The soiled suctions were then observed by pushing a fleece stem from their proximal end to the distal end. The degree of moistness of soil on the fleece stem as well as the soil that came out of the suctions after pushing the fleece stem was noted.

RESULTS

Both the coagulating soils, namely Citrated Sheep's blood coagulated with calcium chloride and Coagulating blood soil applied to medical instruments and kept in the Humipak did not dry out but remained moist up to the time points of 5 days. Soils applied to the control instruments, not in the Humipak, dried within a couple of hours.

The blood soils that were allowed to dry at room temperature for 5 days and then placed in Humipak also rehydrated to a good extent.

The suction tips that sat in the Humipak for 2 hrs and 4 hrs, were observed to be similar to their controls in terms of moisture retention. The control suction tips were still moist after 2 hrs and 4 hrs. However, suction tips in Humipak kept for 2 days and 3 days were observed to be moister than their respective controls. The 3 day time point showed a remarkable difference in the control and the test suction tips. The 3 day control was dried out, whereas the one in Humipak was still wet, indicating its potential use for lumened instruments awaiting cleaning over the weekend or a long travel time to reach their reprocessing location.

CONCLUSIONS

Blood soils on patient used surgical instruments placed in the Humipak do retain their moist state for 5 days. This prevents the drying of blood and bio-contaminants on the instruments and makes it significantly easier for reprocessing by reducing the effort required to clean.

RECOMMENDATIONS

1) Place the patient used instruments in the Humipak as soon as possible after their use.

2) Reprocess as soon as possible.

REFERENCES

AAMI ST79:2010 ***Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities***

ASCRS, AORN: 2007 ***Recommended practices for cleaning and sterilizing intraocular surgical instruments***

Integra™ Jarit® Endoscopic Instruments – Manual Decontamination: Cleaning

ISO/TS 15883-5: 2005 ***Washer Disinfectors- Test soils and methods for demonstrating cleaning efficacy***

Westfield Medical Ltd. ***http://www.westmed.co.uk/humipak.htm***

Westfield Medical Ltd. ***http://www.westmed.co.uk/WML%20Humipak.pdf***