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Physical and composition characteristics of clinical secretions compared with test soils used for validation of flexible endoscope cleaning

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SUMMARY

Aim: To determine which simulated-use test soils met the worst-case organic levels and viscosity of clinical secretions, and had the best adhesive characteristics.

Methods: Levels of protein, carbohydrate and haemoglobin, and vibrational viscosity of clinical endoscope secretions were compared with test soils including ATS, ATS2015, Edinburgh, Edinburgh-M (modified), Miles, 10% serum and coagulated whole blood. ASTM D3359 was used for adhesion testing. Cleaning of a single-channel flexible intubation endoscope was tested after simulated use.

Results: The worst-case levels of protein, carbohydrate and haemoglobin, and viscosity of clinical material were 219,828 μg/mL, 9296 μg/mL, 9562 μg/mL and 6 cP, respectively. Whole blood, ATS2015 and Edinburgh-M were pipettable with viscosities of 3.4 cP, 9.0 cP and 11.9 cP, respectively. ATS2015 and Edinburgh-M best matched the worst-case clinical parameters, but ATS had the best adhesion with 7% removal (36.7% for Edinburgh-M). Edinburgh-M and ATS2015 showed similar soiling and removal characteristics from the surface and lumen of a flexible intubation endoscope.

Conclusions: Of the test soils evaluated, ATS2015 and Edinburgh-M were found to be good choices for the simulated use of endoscopes, as their composition and viscosity most closely matched worst-case clinical material.

Introduction

Reprocessing of re-usable medical devices requires effective cleaning followed by appropriate disinfection or sterilization. Regulatory bodies in most countries require manufacturers to validate reprocessing protocols for re-usable medical devices. Previously, the focus was on validation of the disinfection/sterilization process, but the need for validation of cleaning has been recognized recently. Recent outbreaks of multi-drug-resistant Enterobacteriaceae and *Pseudomonas aeruginosa*, often linked to improper cleaning of flexible endoscopes, emphasize the need for manufacturers to validate their instructions for cleaning medical devices.[1–4] The recently released Food and Drug Administration (FDA) guideline requires manufacturers to validate their cleaning instructions in addition to validation of their disinfection/sterilization instructions.[5] As part of cleaning validation, manufacturers must

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include simulated-use studies.[5] Simulated-use testing, where the device is soiled with an organic test soil, is a critical part of the cleaning validation process.[5] A wide range of test soils have been used, such as 10% serum, coagulated blood, ATS, Hucker's soil, Miles soil, Edinburgh soil etc.[6,7] The FDA guideline recommends that the test soil used for simulated-use testing should represent worst-case conditions, and reflect the type of soil to which the device would be exposed during clinical use.[5] However, few clinical data have been published to help guide the selection of an appropriate test soil. Although coagulated blood is a logical test soil for surgical instruments, the formulations used for other medical devices (e.g. rigid cystoscopes, flexible endoscopes etc.) have been defined less clearly. Many of the test soils in current use represent empiric formulations designed to contain blood constituents and to be difficult to remove. Few reports have been published regarding how the characteristics of various test soils relate to the patient secretions that medical devices are exposed to during clinical use.

The aim of this study was to compare a variety of simulated-use test soils with relevant clinical samples from endoscopes with respect to organic composition, viscosity and surface adhesiveness, and subsequently to compare the optimal test soils by testing the cleaning of a flexible endoscope following simulated use.

Materials and methods

Test soils evaluated

The blood test soil using heparinized sheep blood (CedarLane, Burlington, ON, USA) was coagulated by adding 1 mg protamine sulphate (Sigma, St. Louis, MO, USA) per 1 mL of either whole or 10% heparinized sheep blood. The Edinburgh test soil was prepared as described in ISO/TS 15883-5 Annex N,[6] and consisted of 100 mL egg yolk, 10 mL defibrinated sheep blood (CedarLane) and 2 g Hog mucin (Sigma). The Edinburgh-M (modified) soil consisted of 100 mL egg yolk, 100 mL defibrinated sheep blood (CedarLane) and 2 g Hog mucin. Miles soil consisted of 1 mL sheep blood, 6 g dry milk powder, 10 mL fetal calf serum (Life Technologies Inc, Burlingon, ON, USA) and 1 mL saline (0.9% NaCl). ATS was prepared fresh as per proprietary formulation covered by USA Patent# 6,447,990. The lyophilized ATS2015 version was provided by Healthmark Industries Company Inc. (Fraser, MI, USA), and contained a physiological salt base containing mucin, insoluble cellulose fibre, and reconstituted dried egg yolk with the subsequent addition of 20% sterile sheep blood (CedarLane). The ATS2015 formulation is a revised version of the original ATS formulation. A unique component of ATS2015 is the presence of insoluble cellulose (which is found in patient material such as faeces); this is not present in any of the other currently described test soils.[6]

Clinical samples

Patient secretions were suctioned through duodenoscopes or colonoscopes during clinical procedures (these secretions would normally have been discarded and there were no patient identifiers). To ensure that the suctioned secretions were not diluted, the suction canister was removed at the end of the clinical procedure, prior to bedside flushing of the channels. It was not possible to obtain sufficient suctioned material from the gastroscopes used for clinical procedures. Other clinical samples used for compositional and viscosity testing included urine (samples would normally have been discarded after diagnostic testing, with all patient identifiers removed) and faeces from healthy adult volunteers.

Viscosity testing

Viscosity was measured using a HAAKE rotational viscotester 1 (Thermo Electron GmbH, Karlsruhe, Germany) or a Viscolite 700 vibrational viscometer (Hydramotion Ltd, Malton, UK). Unless specified otherwise, viscosity was measured at 25°C. To ensure that the viscometers were functioning properly, 5 cP (Lot# 13101), 10 cP (Lot # 13101) and 50 cP (Lot # 11101c) viscosity standards (Cannon Instrument Co., State College, PA, USA) were used. The minimum volume to test rotational viscosity (RV) was 100 mL, whereas 20—25 mL of sample was needed to test vibrational viscosity (VV).

Quantitative organic marker assays

The QuantiPro BCA assay kit (Sigma), which includes a bovine serum albumin protein standard and is a quantitative assay based on bicinchoninic acid, was used to quantitate protein. The TMB (3,3′,5,5′ tetramethylbenzadine) liquid substrate system for enzyme-linked immunosorbent assays (Sigma) was used for haemoglobin quantitation, in conjunction with an 80 mg/dL cyanmethemoglobin standard (Stanbio Laboratory, Boerne, TX, USA). The haemoglobin and protein assays were performed in accordance with the manufacturers' instructions, and had limits of detection of 5 μg/mL and 0.5 μg/mL, respectively. Carbohydrate was assessed using the method described by Lui *et al.*,[8] and the limit of detection for this assay was 10 μg/mL.

ASTM D3359 adhesion test

The adhesion test followed the directions for the ASTM D3359 methodology.[9] However, instead of using a visual score, the percentage weight of applied dried test soil that remained after adhesion testing was determined.

Simulated-use testing for cleaning of endoscopes

A comparison of endoscope soiling and cleaning characteristics of optimal test soils was performed using three KARL STORZ Endovision Inc. (Charlton, MA, USA) single-channel flexible intubation endoscopes (Model 11304BC1). The manufacturer's instructions for use were followed for manual cleaning of the scope using the worst-case conditions (i.e. lowest concentration of detergent in the range recommended, fewest passes of the channel brush etc). Enzol (Advanced Sterilization Products, Irvine, CA, USA) was used as the cleaning detergent. The channel was perfused with test soil containing $\sim 10^8$ colony-forming units/mL of *Pseudomonas aeruginosa* and *Enterococcus faecalis*, and excess soil was flushed from the channel. The drying was expedited by flushing additional air through the channel. Two surface sites (insertion tube and control head) were inoculated with 50 μL of the same test soil. The inoculated endoscopes were then held at room temperature for 2 h to mimic routine transit times in clinical