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In-hospital evaluation of orthophthalaldehyde as a high level disinfectant for flexible endoscopes

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Summary: One hundred endoscopes used for bronchoscopy (30), gastroscopy (35) or colonoscopy (35) were studied to determine the efficiency of a new high level disinfectant, orthophthalaldehyde (OPA). Manual cleaning was the method studied since this would be the least effective and thereby provide the greatest challenge to the 0.5% (w/v) OPA solution. The OPA was convenient and easy to use since it did not have irritating vapours and as it is used directly, does not require dilution. Our study demonstrated that the OPA was stable for up to 14 days despite repeated re-use. The cleaning/disinfection procedure could achieve a $\geq 5\ \log_{10}$ reduction in bacterial load. This in-hospital evaluation supports the conclusion that OPA is an effective choice as a high level disinfectant for flexible endoscopes.

Keywords: Orthophthalaldehyde; disinfection; flexible endoscopes.

Introduction

Endoscopy has become a commonplace procedure in the medical field. By far the largest number of such procedures is performed on the respiratory tract (bronchoscopies) or the gastrointestinal tract (gastroscopies or colonoscopies). When endoscopes are used in humans, the instrument is exposed to two broad categories of microorganisms (including bacteria, fungi, viruses and parasites): those that are part of the normal flora, and those that are not normal flora but are primary pathogens. It has been argued that the presence of normal flora in the upper respiratory tract and the gastrointestinal tract precludes the need to use a sterile endoscope. However, subsequent reports have clearly indicated that serious, sometimes life-threatening, infections can be caused by both of the aforementioned groups of organisms. Patient-to-patient transmission of Salmonella spp., Helicobacter pylori, Pseudomonas aeruginosa, Bacillus spp., Serratia spp., and hepatitis B virus (HBV) have been documented. By far the most serious risk of infection occurs when endoscopes are used to access organs such as the pancreas and the gallbladder that are normally sterile. The duodenoscope used for endoscopic retrograde cholangio-pancreatography
(ERCP) passes through the duodenum and instruments are passed through the endoscope into the biliary tree. In almost all cases, nosocomial infections occurring as a consequence of ERCP, were traced to inadequate disinfection of the endoscopes used, or trauma to tissue that resulted in dissemination of bacteria from the colonizing flora. Indeed, Allen et al. demonstrated that, when the duodenoscopes that were used had inadvertently been contaminated with \textit{P. aeruginosa} approximately one-third of the patients developed \textit{P. aeruginosa} biliary tract infections.

Because the endoscope passes over mucous membranes, high level disinfection rather than sterilization is acceptable. The choice of high level disinfectant is of primary concern and detailed guidelines have been formulated to facilitate this decision-making process. The Working Party of the British Society of Gastroenterology has recommended alkaline glutaraldehyde (2%) and Gigasept (10%) as effective antibacterial and antiviral agents that would adequately eradicate both human immunodeficiency virus (HIV) and HBV as well as vegetative bacteria.

The need for activation of 2% glutaraldehyde makes it a labour-intensive disinfectant, and the irritating fumes associated with formaldehyde and glutaraldehyde make these disinfectants difficult to work with. It is apparent that there is a need for an effective high-level disinfectant that requires less handling, has a long shelf-life, and has fewer toxic effects than aldehydes.

In-hospital evaluations of disinfectants have been done for 'targeted' populations. However, in-hospital evaluations of the effectiveness of high level disinfectants for a broad range of instruments that include bronchoscopes, gastrosopes and colonoscopes are limited. This study was aimed at determining if a new high level disinfectant based on the active ingredient, orthophthalaldehyde (OPA) (Johnson and Johnson Inc.), is effective as a disinfectant for these three major types of endoscopes.

\textbf{Materials and methods}

\textit{Orthophthalaldehyde disinfectant}

The OPA solution (0.5\% w/v) was prepared by Johnson and Johnson Inc. It was stored at room temperature and was used directly as a 0.5\% solution. Johnson and Johnson Inc. have conducted in vitro tests and their product label efficacy claims state that OPA (0.5\%) used at 20°C for 5 min is bactericidal for: \textit{Staphylococcus aureus}, \textit{Salmonella choleraesuis}, \textit{P. aeruginosa}; fungicidal for \textit{Trichophyton mentagrophytes}; tuberculocidal for \textit{Mycobacterium bovis} BCG; virucidal for: poliovirus Type 1, influenza virus (Hong Kong strain), herpes simplex virus type 1, herpes simplex virus type 2, adenovirus type 2, vaccinia virus, coxsackievirus type B-3, coronavirus, cytomegalovirus, rhinovirus type 42 and HIV-1; and sporocidal for: \textit{Bacillus subtilis} and \textit{Clostridium sporogenes}. 
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Specimen collection

This ‘in hospital’ evaluation of OPA as a high-level disinfectant of flexible endoscopes was performed at St. Boniface General Hospital (Winnipeg, Manitoba).

A total of 100 endoscopes was assessed after cleaning and disinfection with OPA to determine if there were any residual bacteria, viruses, parasites or fungi. There were 30 bronchoscopes, 35 gastroscopes and 35 colonoscopes evaluated. There were 10 from each group that were also tested immediately after use, i.e. prior to washing or disinfecting, to determine the load of organisms on endoscopes that were used for the three sites indicated. The level of bacteria and fungi was quantitatively determined by preparing serial 1:100 dilutions of the sample and spread-plating 100 μl of each dilution onto blood agar, chocolate agar and MacConkey agar. Detection of viruses, parasites and Clostridium difficile toxin was done using qualitative measurements. The endoscopes were cleaned using protozyme (Ruhof Corp., Valley Stream, N.Y.), disinfected for 5 min at room temperature (≥20°C) with OPA, and then the residual load of microorganisms was monitored by sampling the suction channel. Each sample consisted of approximately 10 ml of antibiotic-free tissue culture medium (RPMI base supplemented with glutamate, and 10% fetal bovine serum) that was drawn through the suction channel. The 10% serum in the tissue culture medium was known to effectively inactivate residual trace amounts of OPA or detergent, thereby ensuring optimal conditions to detect microorganisms. Each 10-ml sample was aliquoted as follows: 1 ml—viral transport media for viral culture; 2 ml—sterile tube for HIV and HBV ELISA tests; 2 ml—mycobacterial culture; 1 ml—in SAF for parasitology; 2 ml—for routine mycological and bacteriological culture and the remaining 2 ml was stored at −70°C. Organisms were identified using standard microbiological procedures. Identification of the organisms to the species level was done when possible using Microscan panels (Baxter Canlab Ltd) or API 20C strips (Sherwood Medical, Plainview, New York).

Gas chromatography assay of orthophthalaldehyde in solution (Direct Injection Method)\(^1\)

The gas chromatography (GC) was performed on a DB-1 column in a varian 3700 GLC using helium as the carrier gas. The injector temperature was 250°C and the detector temperature was 280°C. The run time was 8 min.

Aqueous orthophthalaldehyde was mixed with an internal standard (piperonal) solution in methanol and analysed by gas chromatography. Peak areas were used to calculate the concentration of orthophthalaldehyde in solution.

Viral culture

Viral cultures were performed by routine tissue culture procedures to detect adenoviruses, enteroviruses, herpes simplex virus and myxoviruses. The
ELISA based HIV Ag1 kit (Abbott Laboratories, Abbott Park, IL) was used to detect HIV-1 antigens in the samples drawn through the endoscopes. The 'Auszyme' monoclonal antibody for HBsAg was used in an ELISA-based assay to detect surface antigen of HBV.

Results

The majority of the colonoscopies and gastroscopies were performed for non-infectious disease reasons, whereas the majority of the bronchoscopies were performed to facilitate diagnosis of infectious processes.

A total of 19 batches of OPA were utilized for 14 days each. The temperature of the OPA solution in the trays was measured and all endoscopes were disinfected at $\geq 20^\circ$C. The concentration of orthophthalaldehyde was $> 0.45\%$ of all samples tested. Indeed, there was a slight increase from a concentration on day 1 of $0.55\%$ to $0.59\%$ by day 14. The maximum number of endoscopes disinfected in any one batch of OPA was 16 (Figure 1).

Samples were drawn from 10 bronchoscopes, 10 gastroscopes and 10 colonoscopes after in-hospital use, but before cleaning or disinfecting. This served as baseline data regarding the level of bacterial contamination of these groups of endoscopes. The average load of all types of microorganisms
### Table I. Bacterial and fungal counts (cfu ml⁻¹) from dirty bronchoscopes*

| Organism                  | Mean average cfu ml⁻¹ | No. times isolated | No. bronchoscopes detected in | No. times isolated | No. bronchoscopes detected in |
|---------------------------|-----------------------|--------------------|-------------------------------|--------------------|-------------------------------|
| **Gram-positive cocci**   |                       |                    |                               |                    |                               |
| *Micrococcus* spp.        | 2.00 × 10⁴            | 3                  | 2                             |                    |                               |
| *Staph. aureus*           | 9.68 × 10⁴            | 4                  | 4                             |                    |                               |
| *Staph. epidermidis*      | 2.10 × 10³            | 4                  | 4                             |                    |                               |
| *Staph. haemolyticus*     | 9.00 × 10³            | 1                  | 1                             |                    |                               |
| *Strep. bovis*            | 9.00 × 10⁴            | 1                  | 1                             |                    |                               |
| *Strep. Group F*          | 4.00 × 10⁴            | 1                  | 1                             |                    |                               |
| *Strep. intermedius*      | 1.00 × 10⁴            | 1                  | 1                             |                    |                               |
| *Strep. mitis*            | 4.50 × 10³            | 2                  | 2                             |                    |                               |
| *Strep. pneumoniae*       | 7.50 × 10³            | 2                  | 2                             |                    |                               |
| *Strep. salivarius*       | 1.00 × 10⁴            | 1                  | 1                             |                    |                               |
| *Strep. sanguis*          | 5.07 × 10⁴            | 2                  | 2                             |                    |                               |
| Viridans streptococci     | 1.00 × 10⁴            | 1                  | 1                             |                    |                               |
| **Gram-positive rods**    |                       |                    |                               |                    |                               |
| Diphtheroids              | 5.04 × 10⁴            | 5                  | 4                             |                    |                               |
| **Gram-negative cocci**   |                       |                    |                               |                    |                               |
| *Neisseria* spp.          | 9.70 × 10¹            | 3                  | 2                             |                    |                               |
| **Gram-negative rods**    |                       |                    |                               |                    |                               |
| *Acinetobacter anitratus* | 1.80 × 10⁴            | 1                  | 1                             |                    |                               |
| Haemophilus para-         |                       |                    |                               |                    |                               |
| influenzae                | 6.00 × 10¹            | 1                  | 1                             |                    |                               |
| *Klebsiella oxytoca*      | 1.00 × 10¹            | 1                  | 1                             |                    |                               |
| *Moraxella* sp.           | 1.00 × 10¹            | 1                  | 1                             |                    |                               |
| **Fungi**                 |                       |                    |                               |                    |                               |
| *Candida albicans*        | 1.0 × 10⁴             | 2                  | 2                             |                    |                               |
| *Sacch. cerevisiae*       | 1.0 × 10⁴             | 1                  | 1                             |                    |                               |
| *Exophiala* sp.           | 1.0 × 10⁴             | 1                  | 1                             |                    |                               |

* No viruses were detected.

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on the bronchoscopes before cleaning/disinfection was 6.4 × 10⁴ cfu ml⁻¹. A breakdown of the various groups of bacteria isolated from bronchoscopes is shown in Table I. Streptococci were detected in 8/10 of the dirty bronchoscopes. This reflects the streptococci that are normal upper respiratory flora. The pattern of isolates from bronchoscopes was similar to the baseline data for gastroscopes (Table II). However, it differs in that the average load of microorganisms was higher at 1.7 × 10⁵ cfu ml⁻¹ and the occurrence of isolation of Gram-positive rods was greater (9/10 for gastroscopes vs 4/10 for bronchoscopes). This probably reflects the higher load of diphtheroids in the gastrointestinal tract. The numbers and distribution of microorganisms isolated from the colonoscopes before cleaning/disinfection reflects a very different type of contaminating flora (Table III). The average load of bacteria was 5.2 × 10⁵ cfu ml⁻¹ and was due to the higher concentration of microorganisms in the colon compared to the upper gastrointestinal tract or the bronchi. The predominant bacteria were Gram-negative bacilli (9/10 colonoscopes) and Gram-positive cocci (9/10 colonoscopes). Although Blastocystis hominis was found in two
Table II. Bacterial and fungal counts (cfu ml⁻¹) from dirty gastroscopes

| Organism                  | Mean cfu ml⁻¹ | No. of times isolated | No. of gastroscopes detected in |
|---------------------------|---------------|-----------------------|-------------------------------|
| Gram-positive cocci       |               |                       |                               |
| Micrococcus spp.          | 1.01 × 10⁴    | 3                     | 2                             |
| Staph. aureus             | 2.00 × 10⁴    | 1                     | 1                             |
| Staph. epidermidis        | 5.40 × 10²    | 2                     | 2                             |
| Staph. haemolyticus       | 9.00 × 10²    | 4                     | 2                             |
| Staph. warneri            | 2.00 × 10³    | 1                     | 1                             |
| Strep. bovis              | 5.70 × 10³    | 3                     | 3                             |
| Strep. intermedius        | 1.10 × 10²    | 1                     | 1                             |
| Strep. mitis              | 5.36 × 10⁴    | 5                     | 3                             |
| Strep. morbillorum        | 6.00 × 10³    | 1                     | 1                             |
| Strep. salivarius         | 1.00 × 10³    | 2                     | 2                             |
| Strep. sanguis            | 3.00 × 10⁴    | 1                     | 1                             |
| Viridans streptococci     | 6.29 × 10⁴    | 5                     | 4                             |
| Gram-positive rods        |               |                       |                               |
| Diphtheroids              | 5.14 × 10³    | 15                    | 8                             |
| Lactobacillus sp.         | 1.40 × 10⁴    | 1                     | 1                             |
| Gram-negative cocci       |               |                       |                               |
| Neisseria spp.            | 3.34 × 10⁴    | 3                     | 3                             |
| Gram-negative rods        |               |                       |                               |
| Enterobacter cloacae      | 5.05 × 10³    | 1                     | 1                             |
| Esch. coli                | 1.00 × 10³    | 1                     | 1                             |
| Pseud. aeruginosa         | 9.00 × 10²    | 1                     | 1                             |
| Pseudomonas spp.          | 5.60 × 10³    | 1                     | 1                             |
| Fungi                     |               |                       |                               |
| Candida albicans          | 1.0 × 10⁴     | 2                     | 2                             |
| Candida tropicalis        | 3.8 × 10⁴     | 1                     | 1                             |
| Candida glabrata          | 2.0 × 10⁴     | 1                     | 1                             |
| Penicillium sp.           | 1.0 × 10⁴     | 1                     | 1                             |

* No viruses or parasites were detected.

Colonoscopes, and various fungi were detected, none of the 30 dirty endoscopes sampled contained detectable levels of virus (Table IV).

Each of the 10 dirty bronchoscopes, gastroscopes and colonoscopes was washed and disinfected with OPA. The disinfection consisted of a 5 min soak in OPA at room temperature. Also, a further series of 20 bronchoscopes, 25 gastroscopes, and 25 colonoscopes were washed and disinfected after routine in-hospital use. The average temperature of the OPA solution used to disinfect the 100 endoscopes was 24.1°C (±0.92 SD). The disinfected endoscopes were then sampled according to the method described to determine if there were any residual microorganisms. None of the 100 disinfected endoscopes had residual bacteria, fungi, parasites or viruses. The overall summary of the effectiveness of OPA as a disinfectant is presented in Table IV. This demonstrates that even high levels of bacteria (1 × 10⁶ cfu ml⁻¹) were eliminated to below the limit of detection (10 cfu ml⁻¹); this represented a ≥5 log₁₀ decrease in bacterial counts.

All samples taken from the endoscopes were examined by Gram’s stain. It is of interest to note that, despite cleaning and disinfecting, some of the
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Table III. Bacterial and fungal counts (cfu ml⁻¹) from dirty colonoscopes

| Organism                     | Mean cfu ml⁻¹ | No. times isolated | No. of colonoscopes detected in |
|------------------------------|---------------|--------------------|---------------------------------|
| **Gram-positive cocci**      |               |                    |                                 |
| *Enterococcus faecalis*      | 5.00 x 10⁵    | 1                  | 1                               |
| *Enterococcus faecium*       | 6.50 x 10⁴    | 2                  | 2                               |
| *Micrococcus* spp.           | 1.00 x 10⁶    | 1                  | 1                               |
| *Staph. aureus*              | 1.00 x 10⁶    | 1                  | 1                               |
| *Staph. haemolyticus*        | 2.00 x 10⁵    | 3                  | 3                               |
| *Staph. simulans*            | 3.00 x 10⁵    | 1                  | 1                               |
| *Strep. Group G*             | 2.00 x 10⁴    | 1                  | 1                               |
| *Strep. intermeditus*        | 2.50 x 10⁴    | 2                  | 2                               |
| *Strep. mitis*               | 2.00 x 10⁴    | 1                  | 1                               |
| *Strep. salivarus*           | 4.25 x 10⁵    | 2                  | 2                               |
| *Viridans streptococci*      | 1.12 x 10⁶    | 6                  | 6                               |
| *Streptococcus* sp. (beta haemolytic) | 1.00 x 10⁵ | 1                  | 1                               |
| *Streptococcus* sp. (non-haemolytic) | 1.02 x 10³ | 2                  | 2                               |
| **Gram positive rods**       |               |                    |                                 |
| *Diphtheroids*               | 2.91 x 10⁵    | 10                 | 5                               |
| *Lactobacillus* spp.         | 1.00 x 10⁵    | 1                  | 1                               |
| **Gram-negative cocci**       |               |                    |                                 |
| *Neisseria* spp.             | 7.00 x 10ⁱ    | 1                  | 1                               |
| **Gram-negative rods**       |               |                    |                                 |
| *Citrobacter amalonaticus*   | 1.00 x 10⁶    | 1                  | 1                               |
| *Citrobacter freundii*       | 1.69 x 10⁶    | 3                  | 2                               |
| *Esch. coli*                 | 1.64 x 10⁵    | 9                  | 6                               |
| *Hafnia alvei*               | 3.00 x 10⁵    | 1                  | 1                               |
| *Klebsiella oxytoca*         | 5.00 x 10²    | 1                  | 1                               |
| *Klebsiella pneumoniae*      | 1.07 x 10⁶    | 3                  | 3                               |
| *Proteus penneri*            | 2.00 x 10⁵    | 1                  | 1                               |
| *Pseudomonas aeruginosa*     | 9.00 x 10⁴    | 1                  | 1                               |
| *Serratia marcescens*        | 1.00 x 10⁵    | 1                  | 1                               |
| **Fungi**                    |               |                    |                                 |
| *Candida albicans*           | 1.0 x 10⁴     | 6                  | 6                               |
| *Rhodotorula rubra*          | 1.0 x 10⁴     | 1                  | 1                               |
| *Candida glabrata*           | 2.0 x 10⁴     | 1                  | 1                               |
| *Aspergillus* spp.           | 1.0 x 10⁴     | 1                  | 1                               |
| *Wangiella* spp.             | 2.0 x 10⁴     | 1                  | 1                               |

* In addition, *Blastocystis hominis* was detected from 2 colonoscopes; No viruses were detected.

Stains revealed that bacteria were still present in the endoscopes. A similar pattern was seen for endoscopes disinfected with 2% glutaraldehyde. It is likely that these bacteria were dead, since no viable microorganisms were recovered in culture.

### Discussion

This is the first in-hospital evaluation of the ability of OPA to eradicate microorganisms from endoscopes used for routine medical procedures. Our
Table IV. Overall summary of OPA effectiveness

| Organism          | Dirty       | Disinfected |
|-------------------|-------------|-------------|
| **Bronchoscopes** |             |             |
| Gram-positive cocci | $4.7 \times 10^4$ | 0*          |
| Gram-positive bacilli | $2.8 \times 10^4$ | 0          |
| Gram-negative cocci | $1.3 \times 10^3$ | 0          |
| Gram-negative bacilli | $6.0 \times 10^3$ | 0          |
| Yeast             | $1.5 \times 10^3$ | 0          |
| Other fungi       | $1.0 \times 10^3$ | 0          |
| Parasites         | ND‡         | ND          |
| Virus             | Neg         | Neg         |
| Gastroscopes      |             |             |
| Gram-positive cocci | $1.6 \times 10^4$ | 0          |
| Gram-positive bacilli | $8.5 \times 10^3$ | 0          |
| Gram-negative cocci | $3.4 \times 10^4$ | 0          |
| Gram-negative bacilli | $1.9 \times 10^3$ | 0          |
| Yeast             | $3.6 \times 10^4$ | 0          |
| Other fungi       | $1.0 \times 10^3$ | 0          |
| Parasites         | ND‡         | ND          |
| Virus             | Neg         | Neg         |
| Colonoscopes      |             |             |
| Gram-positive cocci | $2.7 \times 10^4$ | 0          |
| Gram-positive bacilli | $4.6 \times 10^4$ | 0          |
| Gram-negative cocci | $7.0 \times 10^4$ | 0          |
| Gram-negative bacilli | $1.0 \times 10^4$ | 0          |
| Yeast             | $4.0 \times 10^4$ | 0          |
| Other fungi       | $1.5 \times 10^4$ | 0          |
| Parasites‡        | Pos         | Neg         |
| Virus‡            | Neg         | Neg         |

* Limit of detection = 10 cfu ml$^{-1}$; † Quantitation not done, only reported as positive or negative; ‡ ND = Not done for this site.

The baseline data collected from ‘dirty’ endoscopes immediately after use indicated that the load of microorganisms ranged from $6 \times 10^4$ cfu ml$^{-1}$ for bronchoscopes (Table I) to $5 \times 10^5$ cfu ml$^{-1}$ for colonoscopes (Table III).
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This difference is expected because of the different concentrations of normal flora in these body sites, which was less than the $10^9$ cfu ml$^{-1}$ upper range that was reported by Dumon et al. The method of sampling accounts for this, since Dumon et al. reported the concentration of microorganisms isolated in the direct bronchial secretions, whereas, in this study the counts were determined from a 10-ml sample of sterile fluid that was drawn through the ‘used’ dirty endoscope. The types of pathogenic microorganisms isolated from this study were similar to those detected by Dumon et al. Of the ten ‘dirty’ bronchoscopes assessed, nine had bacteria typical of the normal flora of the upper respiratory tract and seven had potentially pathogenic bacteria isolated. None of the bronchoscopes in this study grew mycobacteria (Table IV). Since only 10 dirty bronchoscopes were evaluated and because of the low incidence of tuberculosis in our population, the likelihood of isolating mycobacteria was low.

The types and average load of organisms isolated from the gastrosopes reflected the normal flora of the upper respiratory tract and were similar to those reported by Hanson et al. in patients with AIDS. We did not isolate any H. pylori or viral pathogens (Table IV). This again reflects the study population since the gastrosopies were performed almost exclusively for reasons other than infectious disease.

The higher concentration of bacteria found in endoscopes after colonoscopy (Table III) is expected due to the high concentration of bacteria in the bowel. The patients had fasted prior to the colonoscopy procedure; therefore, although the bacterial load was greater than seen for bronchoscopes and duodenoscopes, it was not as heavy as would be found in direct faecal material. The microorganisms isolated (Table III) reflected the bowel flora where Gram-negative rods are far more prevalent than in either the respiratory tract or the upper GI tract. It is of interest that 6/10 ‘dirty’ colonoscopes were contaminated with Candida albicans (Table III). Indeed, the fungal load was greatest in colonoscopes. The only parasite detected was B. hominis (Table IV) from two of the ‘dirty’ colonoscopes. Since C. difficile can sporulate, it would be of great interest to determine if contamination of endoscopes could result in patient-to-patient transfer. A prospective study by McFarland, Surawicz & Stamm indicated that endoscopy was a risk factor for development of antibiotic-associated pseudomembranous colitis. Although we specifically looked for C. difficile toxin by a selective enrichment procedure, all 10 ‘dirty’ colonoscopes and all of the 35 disinfected endoscopes were negative (Table IV). The small sample size of 10 dirty colonoscopes does not preclude the possible transmission of C. difficile spores and this area requires further evaluation.

Despite an adequate specimen collection, transport, and culture approach, no viruses were detected. These results were similar to those of Hanson et al. where, of the 68 bronchoscopes evaluated, none of the ‘dirty’ bronchoscopes grew any viruses. The negative viral cultures and antigen detection tests indicated that either there were no viable viruses or that the
amount was less than the limit of detection of the tests used. The baseline data demonstrated that, for colonoscopes, the average bacterial load was $5.2 \times 10^5$ cfu ml$^{-1}$. These highly contaminated colonoscopes were still effectively disinfected by OPA. This represented a $> 5 \log_{10}$ reduction in bacterial counts. This in-hospital evaluation demonstrated that a 5 min soak in OPA effectively eradicated microorganisms from bronchoscopes, gastroscopes and colonoscopes (Table IV). The washing process by itself can remove up to $10^3$ organisms, thereby leaving fewer organisms for the disinfectant to kill. This does not detract from our conclusion on the effectiveness of OPA but rather emphasizes the need to combine good washing technique with any high level disinfectant to ensure maximal efficiency of the disinfectant.

The demand for endoscopy procedures has significantly increased over the last 10 years and is expected to continue increasing as new procedures are developed. Indeed, Scott$^{22}$ estimated that, in England, during the 1990s, the annual demand for endoscopy could be 12/1000 population. Recent surveys indicate that cleaning and disinfection procedures may be inadequate in up to 30% of the centres surveyed.$^{23}$ This raises serious concerns regarding infection control. Contaminated endoscopes have been well documented as vectors of not only ‘normal bacterial flora’, but also primary pathogens or water-associated bacteria. Regardless of which disinfectant is utilized, the importance of adequate cleaning cannot be over-emphasized. Regardless of how effective a disinfectant is, if it cannot adequately penetrate the caked-on proteins, is inactivated by too much protein, or is diluted too much, it will be ineffective. The effect of dilution is particularly critical when endoscope washers are used. Care must be taken that adequate quality assurance is done to ensure that the concentration of disinfectant remains within the range of optimal activity. Felmingham et al.$^{24}$ reported that, even if adequate disinfection of endoscopes is achieved, if water is left in the endoscope channels, then the endoscopes will have high bacterial levels after sitting overnight. This was confirmed by Alfa and Sitter.$^{25}$

Ridgway$^{13}$ indicated that a suitable disinfectant should be "microbiologically effective, rapid in action, not significantly affected by organic material, not damage the endoscope and not cause hypersensitivity in the users". With these parameters in mind, this study presents in-hospital data that demonstrate that OPA is an effective high level disinfectant for eradicating vegetative bacteria, fungi and parasites from bronchoscopes, gastroscopes and colonoscopes. Unlike many other high level disinfectants, there is no need to activate or dilute the OPA solution. These features, combined with stability over the 14-day usage cycle, make it an effective alternative choice.

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References

1. O’Connor BH, Bennet JR, Alexander JG, et al. Salmonellosis infection transmitted by fibreoptic endoscopes. *Lancet* 1982; 1: 864.
2. Dwyer DM, Klein EG, Istre GR, Robinson MG, Newmann DA, McCoy GA. *Salmonella newport* infections transmitted by fibre optic and colonoscopy. *Gastrointest Endosc* 1987; 33: 84–87.
3. Langenberg W, Rauws AJ, Oudbier JH, Tytgat GNJ. Patient-to-patient transmission of *Campylobacter pylori* infection by fibreoptic gastroduodenoscopy and biopsy. *J Infect Dis* 1990; 161: 507–511.
4. Doherty DE, Falko JM, Lefkovitz N, Rogers J, Fromkes J. (1982). *Pseudomonas aeruginosa* sepsis following retrograde cholangiopancreatography (ERCP). *Dig Dis Sci* 1982; 27: 169–170.
5. Allen JL, Allen M, Olson MM, et al. Pseudomonas infection of the biliary system resulting from use of a contaminated endoscope. *Gastroenterology* 1987; 92: 759–763.
6. Goldstein B, Abrutyn E. (1985). Pseudo-outbreak of *Bacillus* species related to fibreoptic bronchoscopy. *J Hosp Infect* 1985; 6: 194–200.
7. Webb F, Vall-Spinosa A. Outbreak of *Serratia marcescens* associated with the flexible fibre bronchoscope. *Chest* 1975; 68: 703–708.
8. Siegman-Igra Y, Inbar G, Campus A. (1985). An outbreak of pulmonary pseudoinfection by *Serratia marcescens*. *J Hosp Infect* 1985; 6: 218–220.
9. Birnie GG, Quigley EM, Clements GB, Follet EAC, Watkins G. Endoscopic transmission of hepatitis B virus. *Gut* 1983; 24: 171–174.
10. Sauter G, Grabein B, Huber G, Mannes GA, Ruckdeschel G, Sauerbruch T. Antibiotic prophylaxis of infectious complications with endoscopic retrograde chol-angiopancreatography. A randomized controlled study. *Endoscopy* 1990; 22: 164–167.
11. Rutala WA. APIC guidelines for selection and use of disinfectants. *Am J Infect Control* 1990; 18: 99–117.
12. Working Party of the British Society of Gastroenterology. (1988). Cleaning and disinfection of equipment for gastrointestinal flexible endoscopy: interim recommendations of a Working Party of the British Society of Gastroenterology. *Gut* 1988; 29: 1134–1151.
13. Ridgway GL. Decontamination of fibreoptic endoscopes. *J Hosp Infect* 1985; 6: 363–368.
14. Dawson DJ, Armstrong JG, Blocklok ZM. Mycobacterial cross-contamination of bronchoscopy specimens. *Am Rev Respir Dis* 1982; 126: 1095–1097.
15. Wheeler PW, Lancaster D, Kaiser AB. Broncho-pulmonary cross-colonization and infection related to mycobacterial contamination of suction valves of bronchoscopes. *J Infect Dis* 1989; 159: 954–958.
16. Hanson PJV, Gor D, Jeffries DJ, Collins JV. Chemical inactivation of *HIV* on surfaces. *Br Med J* 1989; 298: 862–864.
17. Johnson and Johnson Inc. Data on file.
18. Johnson and Johnson Inc. Method available on application.
19. Dumon JF, Gevaudan MJ, Mallet MN, Gevaudan P. Effectiveness of basic glutaraldehyde as a disinfectant in bronchial fibroscopy. *Acta Endosc Radiocinematogr* 1977; 7: 405–413.
20. Hanson PJV, Clarke JR, Nicholson G, et al. Contamination of endoscopes used in AIDS patients. *Lancet* 1989; 86–88.
21. McFarland LV, Surawicz CM, Stamm WE. Risk factors for *Clostridium difficile* carriage and *C. difficile*-associated diarrhea in a cohort of hospitalized patients. *J Infect Dis* 1990; 162: 678–684.
22. Scott BB, Atkinson M. Gastroenterology services: a regional review of changes over a five year period (1981–86). *Gut* 1989; 30: 695–700.
23. Frank U, Daschner FD. Disinfection in gastro-intestinal endoscopy: current status. *Endoscopy* 1989; 21: 276–279.
24. Felmingham D, Mowles J, Thomas K, Ridgway GL. Disinfection of gastrointestinal fibrescopes: an evaluation of the Pauldrach Endocleaner and various chemical agents. *J Hosp Infect* 1985; 6: 379–388.

25. Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effects of drying. *J Hosp Infect* 1992; 19: 89–98.