Paediatrica Indonesiana

VOLUME 51 March • 2011 NUMBER 2

Original Article

Properties of endotracheal tubes reprocessed by two procedures

Elisa[1], S.H. Purwanto[1], A.T. Aman [2], Y. Pranoto[3], Kusmono[4]

Abstract

Background Reusing endotracheal tubes (ETTs) has been performed in Indonesia with no evidence of its safety.

Objective The aim of this study was to evaluate sterility, as well as the mechanical, surface, and matrix properties of reused ETTs following 2 different reprocessing procedures.

Methods Reused ETTs were cleaned and disinfected, then sterilized by ethylene oxide gas sterilization (group A) or dry heat sterilization (group B). New ETTs were used as the standard for comparison. Microbes were identified and microbial counts were determined as colony forming units (CFUs). Evaluation of mechanical properties was performed by a Universal Testing machine. All samples underwent tensile and compression tests. Load deformation curves were recorded from F max and strain at F max. Microstructure analysis was done using X-ray photoelectron spectroscopy (XPS), scanning electron microscopy (SEM), and energy-dispersive X-ray spectroscopy (EDX).

Results Positive cultures of commensal bacteria were found in 2/12 samples in group A, and 5/17 samples in group B. There was no statistically significant difference between them (P = 0.07). *Pseudomonas aeruginosa* or other common pathogens were not found. Samples from both groups showed equal flaccidity, compared to the standard. Surface microstructure analysis of reused ETTs with XPS and EDX showed degradation of the matrix component. SEM analysis detected some large particles and fissures. EDX analysis on the large particles detected sodium and calcium signals. Altogether, signs of contamination and material damage were very strong.

Conclusion Both reprocessing methods of reused ETTs gave comparable results on sterility and mechanical behavior, but reprocessing may cause decreased surface and matrix quality. **[Paediatr Indones. 2011;51:73-8]**.

Keywords: *endotracheal tube, reprocessing, reused, microbiological evaluation, mechanical properties, microstructure analysis*

The reuse of single-use medical devices (SUDs) began in the late 1970s.[1] Previously, most devices were considered non-reusable. SUDs are reused as a cost-saving measure.[2] This procedure has regulatory, ethical, medical, legal, and economic implications and has been generated controversy for more than 2 decades. Additional studies are needed to define the risks and document the benefits of reusing SUDs in Indonesia. Reprocessing SUDs could be an alternative for reducing costs and provide a backup in case of decreased availability of imported devices. Until recently, however, there were no standards or evaluations of reprocessing procedures available.

The reprocessing (repeated cleaning, disinfection, and sterilization) of any patient-used narrow-lumen medical devices, such as ETTs, presents a major challenge to hospital reprocessing centers.[2-4] This is further compounded when the narrow-lumen device

From the Pediatric Intensive Care Unit, Jogja International Hospital, Yogyakarta, Indonesia.[1] From the Department of Microbiology, Gadjah Mada University Medical School, Yogjakarta, Indonesia.[2] From the Department of Food and Agricultural Product Technology, Faculty of Agricultural Technology, Gadjah Mada University, Yogjakarta, Indonesia.[3] From the Department of Mechanical and Industrial Engineering, Faculty of Engineering, Gadjah Mada University Yogyakarta, Indonesia.[4]

Reprint requests to: Elisa, MD, Intensive Care Unit, Jogja International Hospital, Jl. Ring Road Utara 160, Condong Catur, Yogjakarta, Indonesia. Tel. +62-274-4463535, Fax. +62-274-411368, E-mail: *elisadewo@yahoo.com*

has been labeled as an SUD. Across the world, there are a variety of approaches in the reuse of SUDs. Reuse of SUDs in Asian, Canadian, and South American countries continues amid controversies about the safety of the practice.[4] Reusing SUDs has been performed in Indonesia without evidence of its safety.

An ETT is used to provide a direct and unimpeded airway to and from lungs. It is commonly made from special non-toxic, clear, thermosensitive siliconized polyvinyl chloride (PVC) material to protect the delicate mucosal tissue and allow confirmation of tube placement due to condensation of expired gases.[5] This device is latex-free. ETTs made of PVC vary widely in their matrix material quality, affecting their reprocessibility, since polymers have lower thermal and chemical stability than other materials.[6] The aim of this study was to evaluate sterility, mechanical, surface, and matrix properties of reused ETTs by two different reprocessing procedures.

Methods

We conducted a study evaluating the reuse of ETTs. Forty ETTs were collected from the Pediatric Intensive Care Unit, Cipto Mangunkusumo Hospital (PICU, CMH), Jakarta with purposive sampling. This sampling method was used due to the limited number of samples. We included all reprocessed ETTs which had been used twice and had no visible damage. All samples were made by the same manufacturer. Reprocessing procedures as independent variables were conducted in 2 different departments in the same hospital. The reprocessing procedure performed in the Neonatal Unit Division was designated as Procedure A, while the reprocessing procedure performed in the PICU division was designated as Procedure B. Procedure A was comprised of manual cleaning using normal detergent dilution, immersion in 2500 ppm of sodium hypochlorite (NaOCl) solution within 2 hours, hung to dry or air-blown dry, put in sterilization packaging, then sterilized with an ethylene oxide gas sterilization device (Anprolene AN74i). Procedure B was comprised of immersion in savlon within 48 hours, manual cleaning using normal detergent dilution, immersion in 5000 ppm of sodium hypochlorite solution within 2 hours, hung to dry or air-blown dry, packed with clean linen, then sterilized with a dry heat sterilization device (Memmert ULE 600 SS oven GmbH+co. KG (Germany). The dependent variables were: sterility (bacterial growth), mechanical performance (strength and ductility), and microstructure assessment, as well as chemical composition of surface and bulk materials.

Microbiological examinations were performed at the Department of Microbiology, Gadjah Mada University Medical School, Yogyakarta, Indonesia. There were 12 used ETTs reprocessed with procedure A and 17 used ETTs reprocessed with procedure B, designated as groups A and B, respectively. All samples were rinsed with sterile, normal saline on the outer and inner surfaces. Rinsing solution was cultured in blood agar, MacConkey agar, Saboroud agar, and thioglycolate agar media (0.1 ml each). All cultures were performed under aseptic conditions. Microbiological study was not performed on new, unused ETTs (standard samples), since they were assumed to be sterile. Microbial colonization detection and identification on cultured samples were done on the 7th day of incubation by microscopy and biochemical reaction testing. The bioburden was expressed as presence or absence of bacterial growth (nominal data). Statistical analysis was done by Fischer's exact test for small samples. Statistical significance was considered at $P<0.05$.

Evaluation of mechanical properties was done by a Universal Testing machine (Zwick, DO-FB0.5TS) at the Department of Food and Agricultural Product Technology, Faculty of Agricultural Technology, Gadjah Mada University, Yogyakarta, Indonesia. We included tensile and compression tests, since we aimed to determine the mechanical characteristics (strength and ductility) of used ETTs in comparison to new ETTs. Four samples were available for each group. Load deformation curves were recorded from F max and strain at F max. For the tensile test, F max was defined as the maximum load in Newtons (N) required for the samples to break. Strain at F max was defined as the percentage of elongation at breakage. For the compression test, F max was defined as the maximum load in Newtons (N) required for the lumen of the samples to crush completely, while strain at F max was defined as the percentage of length reduction before crushing. All mechanical

test results were tabulated in the form of numeric data. Distribution of the means and standard deviations of all parameters were descriptively analyzed with Kolmogorov-Smirnov Z test. All values were compared using Anova. Statistical significance was accepted at $P<0.05$.

The elemental surface composition of the samples was determined by S-probe X-ray photoelectron spectroscopy (XPS, Science Instruments, Mountain View, CA, USA) at the Department of Biomedical Engineering, University Medical Center Groningen/ University of Groningen, Netherlands. The area under each peak was used to calculate peak intensities, yielding elemental surface concentrations for oxygen (O), carbon (C), chloride (Cl), silicone (Si), and nitrogen (N), after correction with sensitivity factors provided by the manufacturer. Element concentrations were examined on the distal inner surface of the tracheal lumen. Increases in chemical elements indicated material changes or contamination.

SEM and EDX were performed by analytical scanning electron microscope (JEOL, JSM-636OLA) at the Marine Geological Institute, Bandung, Indonesia. Surfaces of the samples were analyzed in a line-scanning pattern with SEM. SEM images of the samples were magnified 1000X. Samples were taken at the distal inner part of tracheal lumen from new, unused ETTs (standards) and on reused ETTs from groups A and B. Matrix changes in tube samples and increases in the amount of particles between standards and reused tubes were analyzed. EDX was used in conjunction with SEM in order to identify the composition and chemical characterization of the sample specimens, and their relative proportions. Changes of certain chemical elements and compounds (carbon, oxygen, nitrogen, silicon, sodium, calcium, and chlorine) on reused tubes were deemed to indicate material degradation or presence of disinfection solution residue.

Results

The quantitative cultures of the 12 samples from group A revealed growth of Bacillus species in 2 specimens while cultures of the 17 samples from group B revealed growth of Bacillus species in 5 specimens. No other organisms were detected microscopically or biochemically, in all plates. Statistical analysis revealed no significant difference between these results ($P=0.07$).

The tensile strength test showed that the means of F max and the strain at F max values of group A were higher than those of group B and standard samples. Compression testing showed that the mean F max from groups A and B were lower than the mean F max of standard samples, but the mean strain at F max of all samples were similar. However, those differences were not statistically significant. (**Table 1**)

Under SEM, we detected 'well-arranged' particles on the entire surface of the new tube (**Figure 1**). On

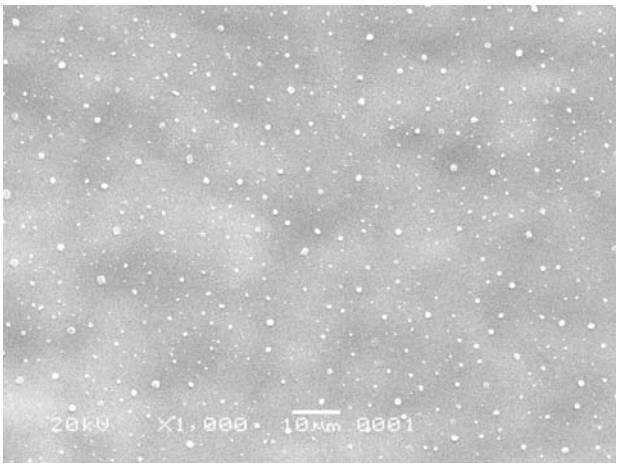

Figure 1. SEM (1,000 x magnification) of a sample from a new tube. Note: "well-arranged" particles on the entire surface.

Table 1. F max and strain at F max among samples

	Standard n = 4	Group A n = 4	Group B n = 4	All groups n = 12	P	P Standard – Group A	P Standard – Group B
Mean F max tensile, Newtons (SD)	76.1 (2.5)	79.2 (6.7)	75.4 (7.1)	76.9 (5.5)	0.630	0.740	0.983
Mean strain F max tensile %, (SD)	132.7 (16.5)	151.8 (30.5)	136.8 (11.7)	140.4 (21.0)	0.439	0.442	0.959
Mean F max compression, Newtons (SD)	54.3 (2.8)	48.8 (3.2)	49.1 (7.3)	50.7 (5.1)	0.257	0.300	0.339
Mean strain F max compression %, (SD)	3.0 (0.0)	3.0 (0.0)	3.0 (0.2)	3.0 (0.1)	0.762	0.748	0.748

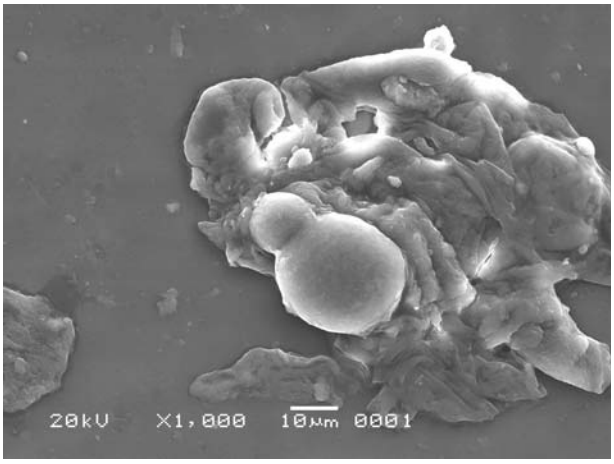

Figure 2. SEM (1,000x magnification) of sample from Group A. Note the degradation and scattering of previously "well-arranged" particles, additional large particles, staining and discoloration.

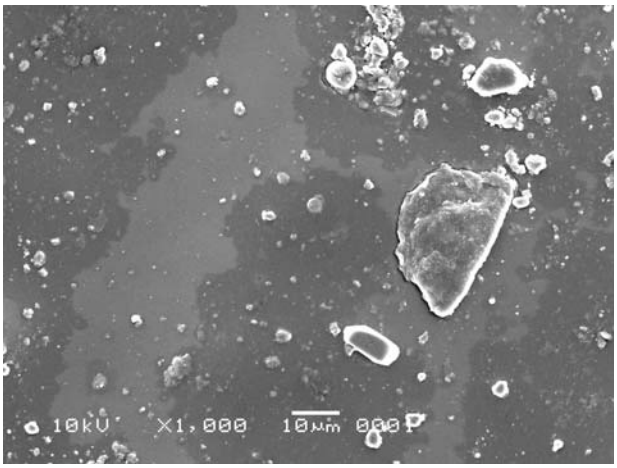

Figure 3. SEM (1,000x magnification) of a sample from Group B. Note the degradation and scattering of previously "well-arranged" particles, additional large particles, staining and discoloration.

reused tubes the previously 'well arranged' particles looked degraded and scattered. Some additional large particles, staining, and discoloration were also evident (**Figures 2** and **3**). Silicon and nitrogen signals were detected only by XPS analysis, not by EDX. This finding indicated that those components were on the surface but not in the bulk property of the material. Under all conditions the compositions determined by EDX and XPS were fairly consistent. (**Table 2**) Oxygen (O) and carbon (C) signals were relatively constant. However, a reduction of chloride (Cl) signal in the reused tubes was comparable to that of the new one. The reused ETT from group A showed enrichment of nitrogen signal, which was not detected in other samples. EDX performed on large particles identified sodium (Na) and calcium (Ca) signals.

Evaluation of ETT mechanical behavior under conditions of tension and compression can provide basic material property data.[14] We used these tests to determine strength, ductility, and toughness of used tubes compared to new ones. Load deformation curves of used tubes appeared more horizontal than curves of new tubes, (**Figure 4**) indicating that the used tubes were more ductile, but less strong and less tough, with clinical implications that there may be higher risk of kinking. However, these differences were not statistically significant, possibly due to the small number of samples tested.

Consistent with the mechanical properties, SEM analysis revealed irregularities and increased number of large particles on the surface of used tubes. Some small fissures were also detected. XPS data showed some differences in the silicone (Si) signal in the used tubes, indicating possible degradation of the surface treatment. Increased surface roughness may be of concern as it would promote bacterial adhesion.[15,16] Lowering of the Cl signal (component of PVC) was evidence of matrix degradation of the used tubes.

Table 2. Results of XPS and EDX analysis

Samples	Analysis	Chemical Elements (Concentration %)				
		O%	C%	Cl%	Si%	N%
New	XPS	11.6	67.5	15.0	5.9	
	EDX	4.58	67.32	28.10		
Used A	XPS	18.9	64.3	4.3	5.6	6.9
	EDX	7.16	73.29	19.55		
Used B	XPS	15.8	70.0	5.7	8.6	
	EDX	6.59	73.57	19.83		

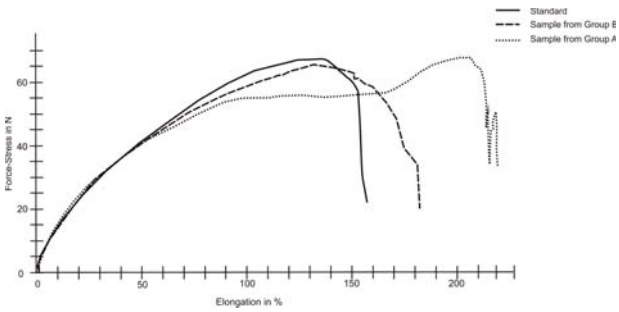

Figure 4. Load deformation curve on tensile test of samples.

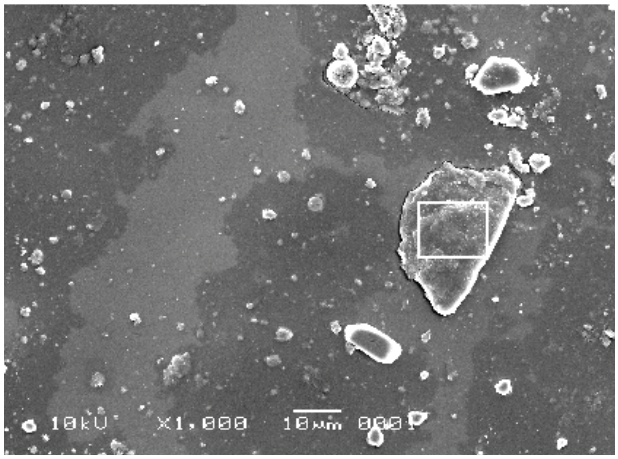

Figure 5. EDX analysis on large particle revealed additional Na (1.80%) and Ca (0.87%) signals.

Enrichment of N signals, as well as Na and Ca signals (from the large particles) indicated contamination on the used tubes (**Figure 5**).

Discussion

Medical devices approved for sale as single use devices are sometimes reprocessed and reused for other patients. Reprocessing should involve cleaning, sterilizing and verifying that it works properly. Reprocessed SUDs are divided into 3 groups: critical reprocessed SUD intended to be in contact with normally sterile tissue or body spaces during use, semi-critical reprocessed SUD intended to be in contact with intact mucous membranes but not penetrate normally sterile areas of the body, and noncritical reprocessed SUD intended to make topical contact but not penetrate intact skin.[7] According to this classification, ETTs are included in the group of critical reprocessed SUDs. The practice of SUD reprocessing raises public health concerns, primarily with regards to the potential risks of infection and device malfunction.[8]

Microbiological data from this study showed that both cleaning and sterilization procedures gave similar results. No Pseudomonas aeruginosa was detected from cultures. Pseudomonas aeruginosa is one of the most prevalent bacterial strains responsible for 30% of nosocomial infections.[9] Merrit et al.[9] showed that, in fact, detergents with surfactants have the capability of cleaning only as effectively as water. However, diluted NaOCl removed bacteria very effectively. Since disinfectant solutions are potent viricidal drugs, a viral protection of the used tubes can be assumed.[10-12] Merrit et al.[9] also showed that both detergents and NaOCl solutions were effective in removing blood which often contaminates medical devices cleaned for reuse.

Although ethylene oxide (EO) sterilization is used ubiquitously in sterile processing with a variety of instrumentation and is known to eliminate microbiologic contaminants, the compound itself has toxic potential. Therefore, a waiting period before reuse or detoxification after EO sterilization has been shown to be warranted.[13] Since EO gas reagent is relatively expensive and must be imported, dry heat sterilization is also used as an alternative method of sterilization. This method is considered lower in cost and simpler in procedure. A disadvantage of using the dry heat method is that it may exceed the maximum temperature which can be withstood by PVC material.[6,12] In addition, to effective disinfection and cleaning, including the removal of residual soils and particles from all surfaces, adverse effects on the surfaces and matrix structure should be avoided during reprocessing.

This study restricted testing to one brand of ETTs, which was considered the best in quality in our setting. Our findings may not be applicable to ETTs from other manufacturers. Extension and modes (nasally or orally) of intubation may also influence used ETT performance.

We have shown that both reprocessing methods of twice reused ETTs gave comparable results on sterility. The reused tubes retained their mechanical performance compared to new ones. However, there were some tendencies of weakening in the reused tubes, although, statistically, a larger sample

size may be required to determine significance. In accordance with our findings, surface roughness, matrix degradation, and evidence of contamination of used tubes may be reasons to look for better reprocessing methods.

In conclusion, both reprocessing methods of reused ETTs gave comparable results on sterility and mechanical behavior, but reprocessing appeared to decrease surface and matrix quality.

Acknowledgments

We thank to Titik Nuryastuti MD, Rachmat, Wikanda, Andaru D. Dewi , and Prof. H.C. van der Mei for their assistance.

References

1. Rutala WA, Weber, DJ. Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for disinfection and sterilization in healthcare facilities. [cited 2010 October 27]. Available from: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection _Nov_2008.pdf
2. Pyrek KM. Reprocessing update: FDA continues its scrutiny of premarket submissions as healthcare professionals debate patient-safety issues. 2002. [cited 2010 October 27]. Available from: http://www.infectioncontroltoday.com/articles/2002/02/ reprocessing-update.aspx
3. Nanta P, Senarat W, Tribuddharat C, Danchaivijitr S. Cost-effectiveness and safety of reusable tracheal suction tubes. J Med Assoc Thai. 2005;88:S86-8.
4. Alfa MJ, Nemes R. Inadequacy of manual cleaning for reprocessing single-use, triple lumen sphinctertomes: Simulated-use testing comparing manual with automated cleaning methods. Am J Infect Control. 2003;31:193-207.
5. Portex Blue Tracheal Tube. Product Manual. [cited 2010 October 27]. Available from: http://www.goodman.hk/html/portex.html
6. Lee HB, Khang G, Lee JH. Polymeric Biomaterials. In: Bronzino JD, editor. The Biomedical Engineering Handbook. 2nd ed. Connecticut: CRC Press LLC; 2000. p. 39-1 – 39-23.
7. Zimmerman BA. Medical Devices: Reprocessed single-use devices; Termination of exemptions from premarket notification; requirement for submission of validation data. Federal Register. 2005;70:56911-22.
8. Ayzman I, Dibs SR, Goldberger J, Passman R, Kadish A. In vitro performance characteristics of reused ablation catheters. J Intervent Cardiol Electrophysiol. 2002; 7:53-9.
9. Merrit K, Hitchins VM, Brown SA. Safety and cleaning of medical materials and devices. J Biomed Mater Res. 2000; 53:131-6.
10. Lipp MDW, Jaehnichen G, Golecki N, Fecht G, Reichl R, Heeg P. Microbiological microstructure, and material science examinations of reprocessed combitubes® after multiple reuse. Anesth Analg. 2000;91:693-7.
11. NHS Scotland Property & Environment Forum. Decontamination-cleaning, disinfection & sterilization. 2003.
12. Cleaning, disinfecting, and sterilizing plastics. [cited 2010 October 27]. Available from: http://www.gordonbrush.com
13. Merckx J, Kinget R. Ethylene chlorohydrin determination in ethylene oxide sterilized polyvinyl chloride tubing. J Clin Hosp Pharm. 1986;11:357-63.
14. Rhim JW, Weller CL. Properties of formaldehyde adsorbed soy protein isolate films. Food Sci Biotechnol. 2000; 9:228-33.
15. Balazs DJ, Triandafillu K, Chevolot Y, Aronsson BO, Harms H, Descouts P, et al. Surface modification of PVC endotracheal tubes by oxygen glow discharge to reduce bacterial adhesion. Surf Interface Anal. 2003; 35:301-9.
16. Gottenbos B, Busscher HJ, Van der Mei HC, Nieuwenhuis P. Pathogenesis and prevention of biomaterial centered infections. J Mater Sci Mater Med. 2002; 13:717-22.