An Analysis of Micro-embolic Particles Originating in the Extra-corporeal Circuit Before Bypass

J. V. Pastoriza-Pinol, C.C.P.*; J. McMillan, C.C.P.*; B. F. Smith, C.C.P.*; M. Sandy, B.Sc.**; C. Lancucki, B.Sc.**; G. R. Stirling, F.R.A.C.S.***; and P. E. Newland, F.F.A.R.A.C.S.

* Alfred Hospital, Melbourne, Australia; ** C.S.I.R.O., Melbourne, Australia; and *** Director of Cardiac Surgery, Alfred Hospital, Melbourne.

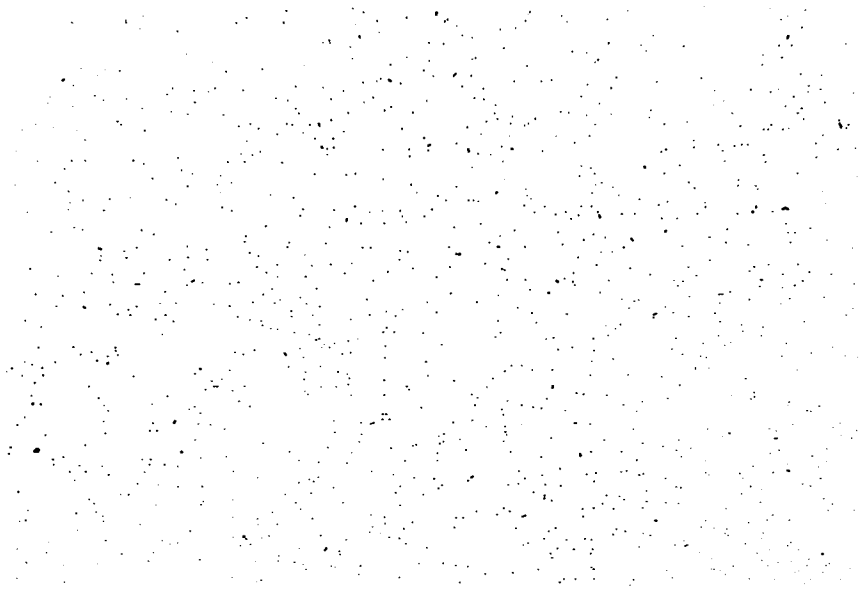
INTRODUCTION

Particulate micro-embolism is a serious threat to the patient in all cardiopulmonary bypass operations. It has been found previously that after priming there are numerous particles present in cardiopulmonary bypass circuits, though their exact composition has been uncertain.[1] The purpose of the present study was to determine the composition of particulate matter originating in the extra-corporeal circuit using the technique of x-ray diffraction (XRD) and scanning electron microscopy (SEM). In over 1,000 procedures using six different types of oxygenators, a 5 micron millipore filter was used to trap particles circulating in the priming solution prior to bypass. Particles from the filters were analyzed. There were 870 filters from extra-corporeal circuits incorporating bubble oxygenators and 153 filters from extra-corporeal circuits incorporating the microporous membrane oxygenator (TRAVENOL TMO*).

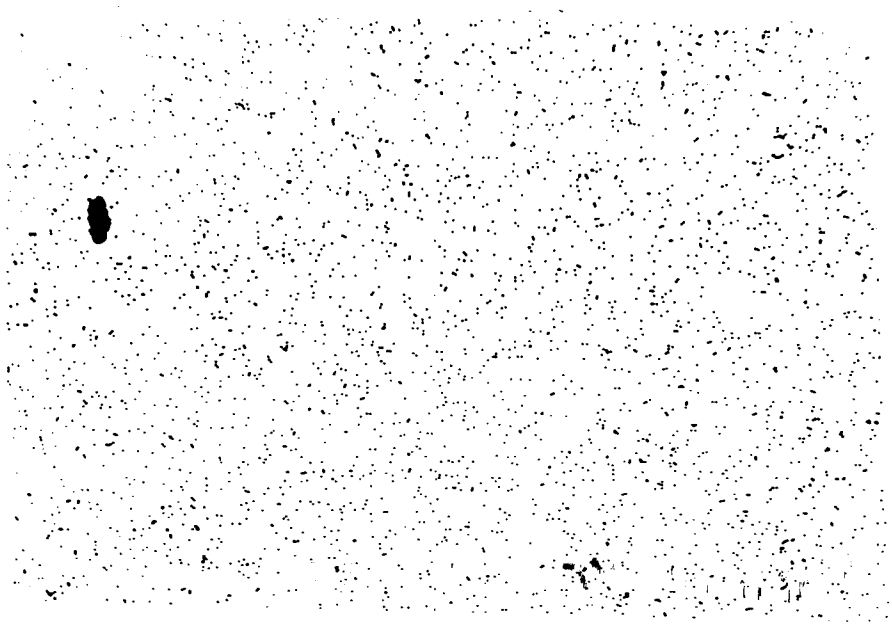
METHODS

In 870 extra-corporeal circuits using bubble oxygenators and in 153 circuits using a microporous membrane oxygenator (TRAVENOL TMO), a 5 micron MILLIPORE (SMWP 47) filter was placed in the pump recirculation line distal to a PALL ULTIPOR** (EC3840) arterial line filter. However, for the T.M.O. circuit this arterial line filter was omitted. The P.V.C. medical formulation tubing used in these circuits had been previously washed with detergent, rinsed with ultra-distilled water and dried with filtered medical air. The circuit prime used was 1.5 litres Plasmalyte 148 in water and 1 litre Plasmalyte 56 in 5% dextrose. Heparin injection BP (MUCOUS) was added at a ratio of 4 units Heparin to 1 millilitre of Plasmalyte. This solution was recirculated for 10

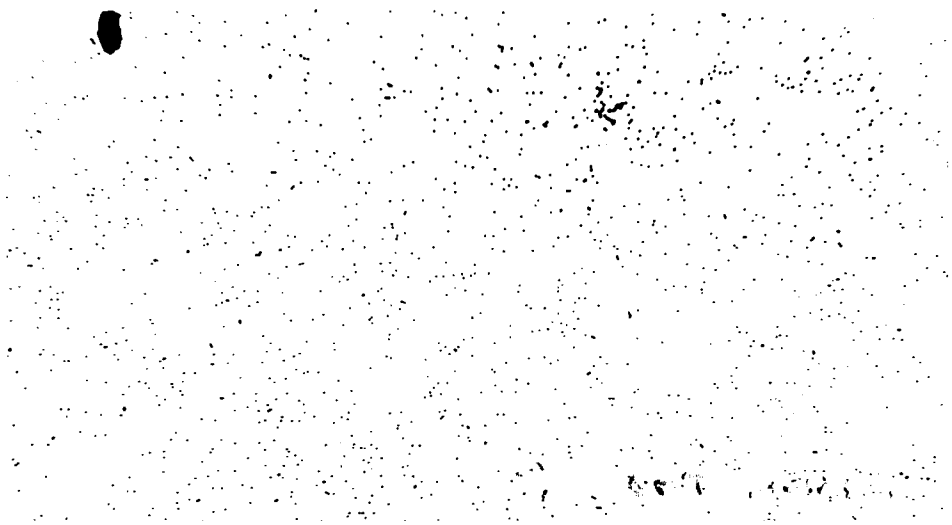
* Travenol Laboratories, Inc. Artificial Organs Division, Deerfield, IL 60015.
** Pall Biomedical, Glen Cove, NY 11542.



Travenol TMO



Polystan RK



Polystan VT

TABLE I

87 Polystan*	VT5000
431 Polystan	RK5000
257 Harvey Hybrid**	H1000
28 Cobe Optiflo***	42-2001
67 Bentley Temptrol****	Q200A
157 Travenol TMO	5M-03-16

* Polystan, Herlev, Denmark
** Wm. Harvey, Santa Ana, CA 92705
*** Cobe Laboratories, Lakewood, CO 80215
**** Bentley Laboratories, Irvine, CA 92714

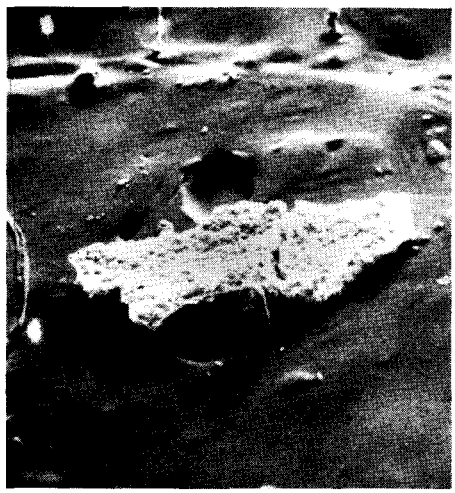
minutes at 2.5 litres per minute. Naked eye observation of used filters was recorded in 1,023 extra-corporeal circuits incorporating the oxygenators listed in Table I.

One filter from a Polystan RK circuit and one from a Polystan VT circuit were submitted to SEM. From the abundant supply of particles on these filters, 11 were taken from each filter and underwent SEM. In addition, 11 photographs were taken during the scanning of these particles (five from Polystan RK and six from Polystan VT). Studies of silicone distribution were undertaken on a total of three other filters. One from a Polystan RK, one from a Polystan VT, and one from a Travenol TMO circuit. SEM and XRD were performed on a 6 × 6 mm. area randomly taken from each of these filters.

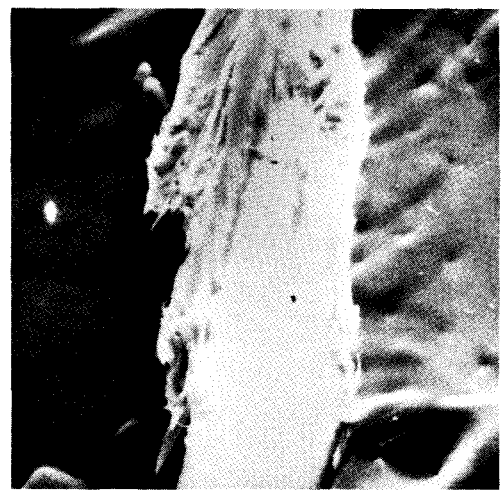
TABLE II
SEM of Polystan RK Circuit

Particle	Description	Elements	Size
1	White fibre	Si, Al	
2*	White grain	Si	400 μ
3*	Grain of white and brown mixture	Si, Al	360 μ
4*	Orange brown grain	Al	500 μ
5	White grain	Si	
6	Brown grain	Si, Al	
7*	Orange brown grain	Si, Al, Fe	400 μ
8	Black fibre	(ND)	
9	White long grain	(ND)	
10*	Black long grain	Fe	350 μ
11	White long grain	(ND)	

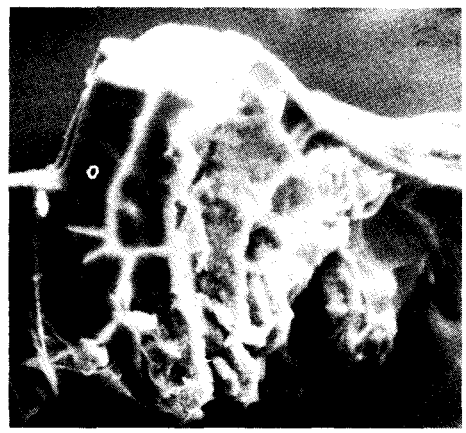
(ND) = Non detectable elements: plastics, H, He, Li, Be, B, C, N, O, F, Ne.
* See photo.



Particle 2

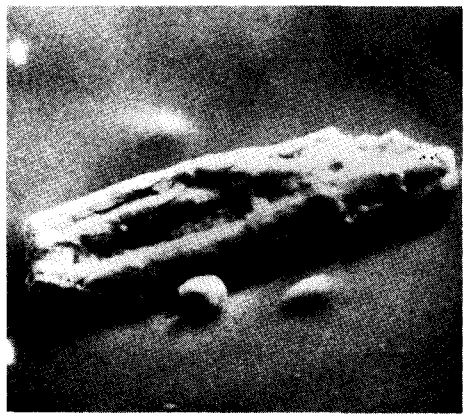


Particle 3



Particle 4

Particle 7

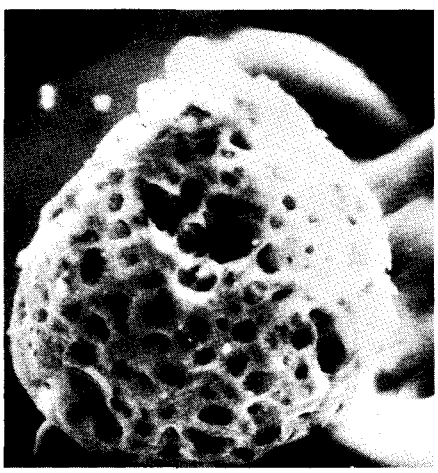


Particle 10

TABLE III
SEM of Polystan VT Circuit

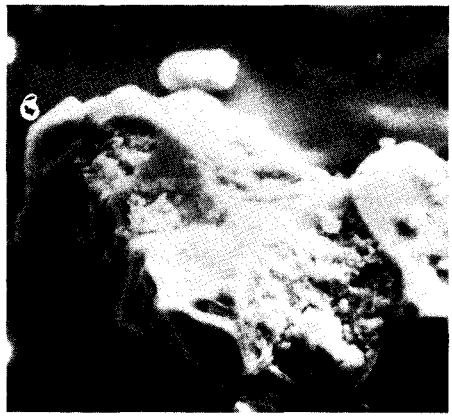
Particle	Description	Elements	Size
1*	Round black grain	S	380 μ
2	White fibre	Si	
3	White fibrous grain	Si	
4	Black grain	Fe, Si, Al	
5*	Brown grain	Si, S	360 μ
6*	Black grain smooth crystal and coating	Fe, Si, S, Al	400 μ
7	White grain	(ND)	
8*	Small white speck	Si	30 μ
9*	Brown grain	Si	600 μ
10	White and light brown grain	(ND)	
11*	Small white speck	Si	60 μ

(ND) = Non detectable elements: plastics, H, He, Li, Be, B, C, N, O, F, Ne.
* See photo.

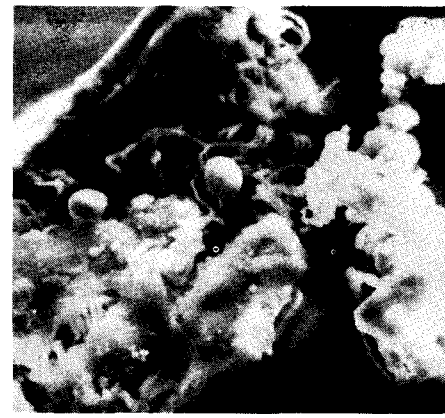


Particle 1

Particle 5



Particle 6



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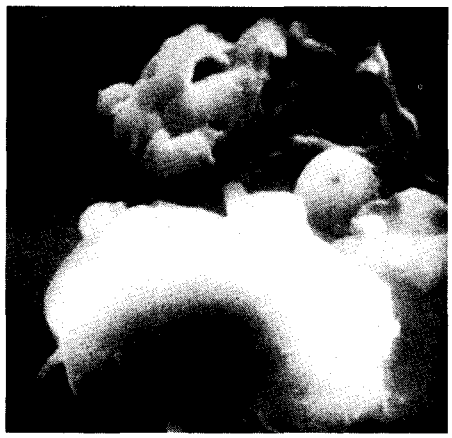
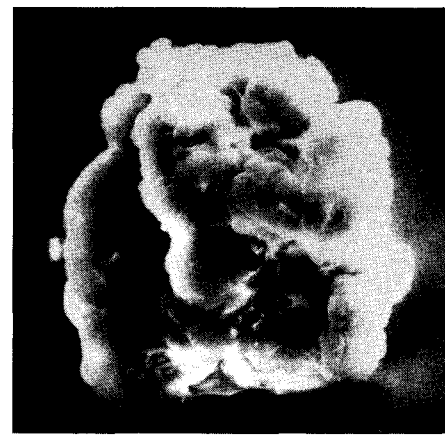


Particle 8



Particle 11

TABLE IV

Circuit	Element	Counts
Polystan RK*	Silicone	2,260
Polystan VT*	Silicone	1,480
Travenol TMO*	Silicone	420

Number of counts per 100 seconds at ×100 magnification
* See photo.

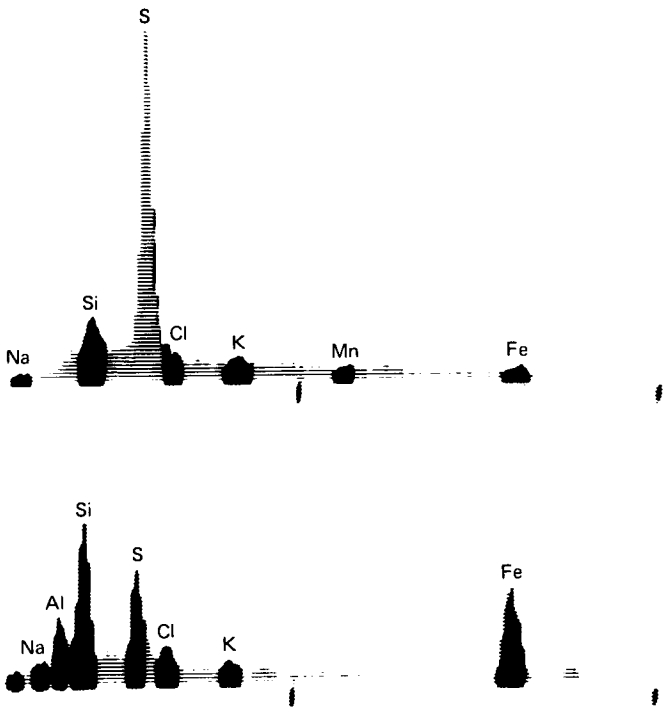
RESULTS

Recording of naked eye observations of filters made immediately after use showed that all of the 870 filters used in the circuits incorporating bubble oxygenators had particles clearly visible. Conversely, all of the 153 filters used with the circuits incorporating the TMO oxygenators appeared to be free of particles. SEM analysis of the 11 particles

from Polystan RK (Table II) showed the major component in the particles to be silicone, which is present in sizes ranging from a small grain of salt ($\simeq$600 microns), down to colloidal silica in solution (less than 1 micron). The eleven particles from Polystan VT (Table III) were of similar size and composition except for the presence of sulphur which occurs in this group of particles.

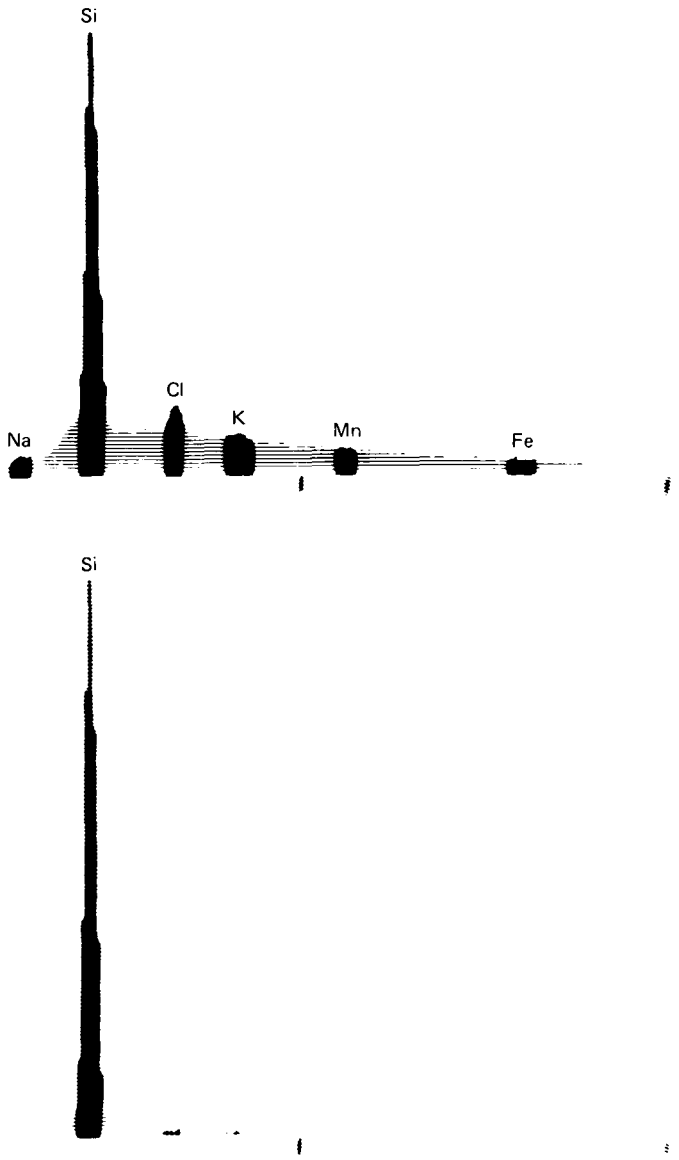
SEM photographs taken during silicone distribution studies (performed on the three filters taken from the Polystan RK, Polystan VT and Travenol TMO circuits) showed an even distribution of small particles of silicone throughout the three filters.

However, the particle density was far greater for the bubble oxygenators than for the microporous membrane (see Table IV and photographs). That the particles photographed at SEM were indeed silicone is supported by the negative XRD result, a technique that fails to detect substances with no crystalline structure.



CONCLUSION

This study confirms the presence of a large number of particles in the extra-corporeal circuit before institution of cardiopulmonary bypass, despite cleaning measures undertaken to remove them. Analysis of their composition reveals the predominance of silicone, usually coating other substances to form larger particles or fibres. The presence of sulphur in particles seen in the filter from the Polystan VT circuit may have originated from welding of the stainless steel heat exchanger present in this unit. There were no particles microscopically visible on prebypass filters used in conjunction with the microporous membrane. This reflects the value of the membrane oxygenator as a filter. There were



pure silicone particles less than 1 micron in size detected by SEM and XRD when the microporous membrane was used, although they were far less numerous than with the two bubble oxygenators. The silicone particles seen with the membrane oxygenator must have originated from the defoaming chamber of the cardiotomy reservoir. We feel that prebypass filtration is a necessary adjunct to preparation for extra-corporeal circulation. This is especially so for bubble oxygenators.

REFERENCE

1. Reed, C., AM.S.E.C.T. Int. Conference, July 1974, Dallas, Texas, U.S.A.