REDUCTION OF SILICONE PARTICLE RELEASE DURING HAEMODIALYSIS

J Bommer, *E Pernicka, J Kessler, E Ritz

University of Heidelberg, *Max-Planck-Institut für Kernphysik, Heidelberg, FRG

Summary

Spallation of silicone was evaluated in an in vitro system, using a commercial blood pump and dialysis tubing. Silicone particle release was assessed at various occlusion forces (5.5–22 kp). When the occlusion force was reduced from 22 to 5.5 kp, the number of released silicone particles decreased by ~ 80 per cent; in parallel, the amount of silicone retrieved from the recirculation fluid decreased from 1.6mg to less than 0.23mg. It is concluded that reduction of occlusion pressure within the blood pump effectively reduces spallation of silicone tubing.

Introduction

Spallation of silicone dialysis tubing and deposition of silicone particles in the viscera of haemodialysis patients has recently been described by several authors [1–5]. Several clinical abnormalities have been related to particle loading of visceral macrophages, e.g. elevated transaminases and granulomatous hepatitis, hepato-splenomegaly and hypersplenism with pancytopenia [6]. In addition, in experimental studies, alteration of macrophage function with increased prostaglandin synthesis could be demonstrated when rats were loaded with silicone, PVC or polyurethane particles by intravenous or intraperitoneal injection [7].

Studies from this laboratory [8] and from other investigators [3], using scanning electronmicroscopy, demonstrated extensive damage on the luminal surface of dialysis tubing after exposure to a roller pump for five hours. Previous investigators using chloroform extraction procedures gave low figures for silicone release, i.e. 50μg per five hours of haemodialysis; however, particle load may have been underestimated since the procedure used allows only measurement of soluble silicone oligomers [2].

The present in vitro study was designed to further quantitate the amount of silicone release under conditions closely imitating the haemodialysis procedure.
Particle release was quantitated by counting and by direct silicone measurements without prior extraction steps.

Material and methods

A recirculation system with a priming volume of 300ml saline was set up. The system consisted of a commercial roller pump (Fresenius Co), silicone tubing for the roller pump insert (internal diameter 8mm, wall thickness 1.8mm) and PVC tubing for the non-roller pump segments. The pump operated at 25rpm=280ml/min. The occlusion force was varied over a range from 5.5–22 kp by adjusting the distance between the roll and the abutment using spring coils with defined forces. The pressure was directly measured with commercial calibrated gauges.

After five hours the priming fluid was assessed for silicone particles both by measuring silicone concentration with atomic absorption spectrophotometry and by counting silicone particles microscopically.

Silicone was measured using a Perkin Elmer atomic absorption spectrometer 430 with a pyrolytically coated graphite tube and programmed temperature control. A 25μl sample was dried (100°C; 60 sec), decomposed (350°C; 60 sec) and atomised (1950°C; 8 sec). Sodium silicate diluted in NaOH was used as standard solution. Appropriate blanks and internal standards were used throughout. All measurements were done in triplicate. Detection threshold was 0.2ppm and the coefficient of variation of replicate measurements was ~ eight per cent at 0.5ppm.

For counting silicone particles, the fluid was filtered through a Millipore filter (exclusion limit 0.025μ). The filter was rendered transparent by silicone oil. Particles were counted using a light microscope (x 500) with a counting grid. The method was compared with counting in a Neubauer chamber which generally yielded much lower values. This was ascribed to particle loss during transfer into the counting chamber. The values given in Table I refer to counting on a Millipore filter.

Results

As shown in Table I, at an occlusion force of 22 kp 20.3 x 10^6 silicone particles >0.3μ per ml recirculation fluid were released; this would be equivalent to a silicone particle load of 6 x 10^9 particles per dialysis session. This figure will

<table>
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<tr>
<th>TABLE I. Number of particles and amount of silicone released at different occlusion pressures (n=6 experiments)</th>
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<tr>
<td>22 kp</td>
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<tr>
<td>number of particles (10^6/ml)</td>
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<td>total amount of silicone (mg/5hr)</td>
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* detection threshold
even underestimate the total number of particles since fragments <0.3μ could not reliably be detected microscopically. Reduction of the occlusion force significantly (p<0.01) reduced generation of silicone particles.

This finding was validated with an independent technique, i.e. measuring silicone release into the recirculation fluid with flameless atomic absorption spectrometry. Silicone tubing (polydimethylsiloxane) has a silicone content of 26 per cent (information obtained from the manufacturer); this figure was used to calculate silicone release on the basis of silicone measurements.

Reduced fragmentation of dialysis tubing at lower occlusion pressure would be compatible with qualitative electronmicroscopic observations of the luminal surface of the tubing, even when the large sampling error is considered (Figure 1).

![Figure 1. Scanning electronmicrograph of luminal surface of silicone tubing after five hours exposure to a roller pump (x 1000). Note 'hillocks' projecting over and several particles adhering to luminal surface](image)

**Discussion**

The present experiments clearly demonstrate that appropriate adjustment of the occlusion pressure in the roller pump permits a reduction in the calculated annual silicone load in haemodialysis patients from 250mg/year to 36mg/year (i.e. per 150 dialysis sessions). This observation is easily explicable by reduction of non-elastic deformation of silicone tubing with reduced pressure. Such deformation causes fragmentation of the luminal surface (as demonstrated with SEM) and release of elastomer particles. The effect of occlusion pressure is also illustrated by measurements of the distance between abutment and
roll at varying occlusion forces. For tubings used in the above experiment, the distance was 2.9mm at 22 kp and 3.5mm at 5.5 kp. Since total wall thickness was 2 x 1.7–1.8mm, these figures document considerable deformation of tubing wall at high occlusion pressure.

From the above studies over-occlusion emerges as a major factor responsible for particle release. Only future studies will determine whether it will be sufficient to optimise occlusion pressure in order to avoid particle related clinical problems or whether changes of dialysis equipment will be required, e.g. use of more resilient silicone tubing or introduction of membrane pumps.

References

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