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Extracorporeal Tubing in the Roller Pump Raceway: Physical Changes and Particulate Generation

Allison J. Bednarski Spiwak, MS; Alexander Horbal, BS; Robert Leatherbury, BS; Derek J. Hansford, PhD

Circulation Technology Division and Department of Biomedical Engineering, Microfabrication, The Ohio State University, Columbus, Ohio

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Abstract: Plasticized polyvinyl chloride tubing is used as the blood conduit in the heart lung bypass circuit. The section in the roller pump undergoes rigorous compression. Fatigue leads to material changes in weight and length of the bulk material. Particles are released during normal pump operation. This study evaluates the time course of particle loss. Three segments of ½″ ID tubing run in the raceway for 30-minute, 1-hour, or 2-hour. The fluid path of each segment includes an oxygenator; a castor oil blend was used for the prime. The 5 mL sample was acquired at 10 minute intervals. Raceway tubing segments were measured for a change in weight and length. The same procedure repeated with ¼″ ID and ⅜″ ID tubing. All tubing increased at least 5 mm by the 2-hour trial. There were no remarkable changes in weight. Particles were measured for size and percent volume. Tubing with ½″ ID performed most consistently for particle release during all trials. Particles were observed as small as 1 nm. Particles as large as 3 micron could be confirmed. For all tubing there was particle release by 30 minutes. Perfusionists must consider tubing inner diameter and wall thickness in choosing the pPVC for the raceway in order to minimize particulate emboli. This research suggests that ⅜″ ID tubing produces spalls inconsistently compared to ½″ ID tubing. Thinner wall thickness tubing also has the potential to limit spall formation. **Keywords:** di-2-ethylhexyl phthalate, polyvinyl chloride, tubing, spallation, fatigue. *JECT. 2008;40:188–192*

Plasticized polyvinyl chloride (pPVC) tubing is used as the blood conduit in the heart lung machine. During cardiopulmonary bypass (CPB), this tubing is put under aggressive treatment by the roller heads. The roller head compresses the pPVC against the backing plate of the pump housing to propel the blood out of the tubing segment. This rigorous challenge leads to changes in the material properties of the pPVC. Changes to the material include loss of plasticizer and gain of blood path constituents such as water and pharmaceuticals (1–6). Plasticizer loss was caused by compression, leaching, and evaporation (1).

Spallation occurs when particles generate and release from the tubing. This process is known to occur in the raceway of the roller pump during normal pump operation (7–15). Images of the surface taken by scanning electron microscopy (SEM) show this process of particle formation (7–17). Tubing out of the packaging does not show the same process (10). SEM images show particle dimensions from 10 to 150 μm. Images by atomic force microscopy (AFM) show particles with 10-nm dimensions representative of changes in surface coating familiar to some products (12). The study by Uretzsky et al. (7) shows that spallation occurs rapidly in both uncoated pPVC and silicone tubing.

Medically, the concern is that release of foreign materials unfamiliar to the body might activate acute and chronic pathologies. Rossi and Schettler (18), in a white paper, "PVC & Healthcare," highlighted the exposure to plasticizer phthalates, specifically di-2-ethylhexyl phthalate (DEHP). Phthalates pose risk to reproduction, hepatomegaly, and can result in acute immune system response (3,18–22). As a consequence, the European Union (EU) restricts exposure to 48 μg/kg/d, which can be exceeded during a plasmapheresis session (19–22). There is common use of alternative pPVC or silicone pump boots in the EU. Alternative pPVC is available that does not use DEHP, and preliminary evaluation by SEM showed few if any fatigue patterns in 6 hours of exposure to roller pump treatment compared with traditional pPVC (Figure 1) (12,22).

The purpose of this experiment is to examine the aggressive treatment of tubing in the raceway. The goal is to examine physical properties and particle release during

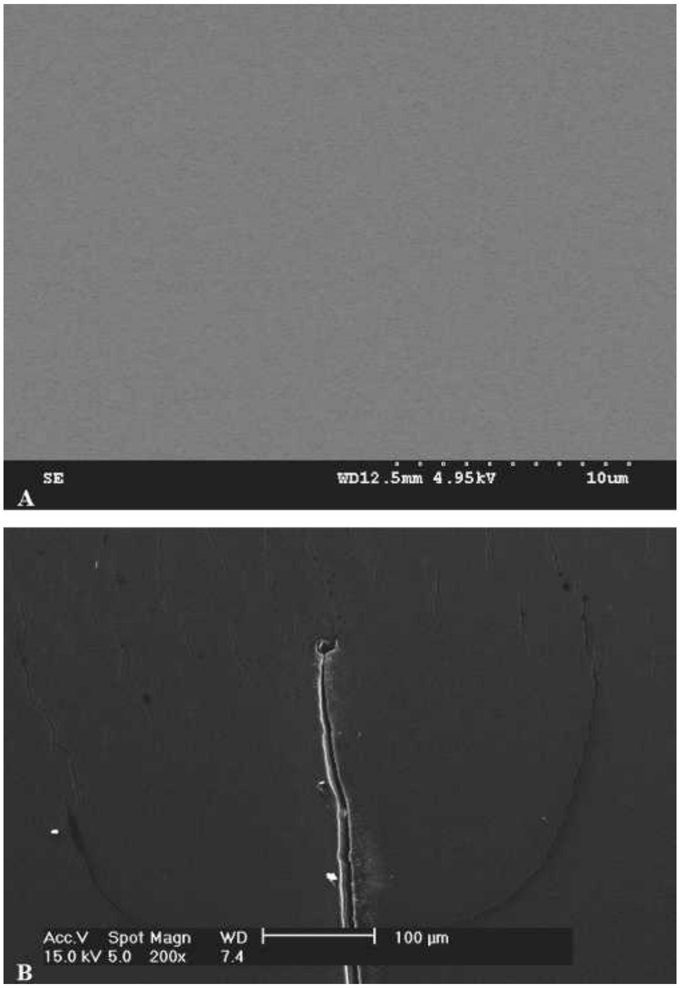

Figure 1. Plasticized PVC. A, Tygon S-95-E tubing. Tubing inner surface after 6 hours of treatment by roller head pump > 100 rpm. Image width is ~30 µm across. Notice there were no distinctive patterns on the image. B, Traditional pPVC with DEHP after exposure to roller head compression. The surface suffers from cracks, craters, and material irregularities.

rigorous pump runs. The changes in physical and material properties may include changes in weight, length, and plasticity (3,11,14,23). Therefore, we will evaluate blood path tubing for CPB with different inner diameters (IDs) and different wall thicknesses. A trend in particle release may be an indicator of material stability for the purpose of CPB. Particle release may be limited to a specific time course based on tubing ID or wall thickness.

MATERIALS AND METHODS

Roller pumps (COBE Century, Arvada, CO) were prepared for different ID tubing. The necessary tubing guards and occlusions were set to accept ¼″, ⅜″, or ½″ pPVC tubing. Uncoated pPVC was chosen for the experiment. The tubing was taken from a collection of donated CPB custom tubing packs. Tubing sizes of ½″, ⅜″, and ¼″ ID had outer wall thicknesses of 3⁄32″, 3⁄32″, and 1⁄16″, respectively. Three segments of the ½″ ID tubing were cut to the length of the raceway. Before insertion, the tubing was measured for length and weight. The segments were loaded into the raceway against the backing plate. "Just under occluded" setting was followed per manufacturer instructions. The extracorporeal circuit path included polycarbonate connectors with luer lock to connect the test segment to ⅜″ ID pPVC and a hollow fiber oxygenator with integral heater exchanger. The high flow stopcock on the luer lock distal to the raceway was used for sampling. Perfusate temperature was maintained at 32°C.

Perfusion solution was made of a mixture of 200 mL castor oil and 800 mL saline to encourage surface changes similar to other body fluid solutions (24). Castor oil is naturally occurring and inexpensive. Its amphiphilic nature is surface active. A viscous, non-volatile and non-drying oil, castor oil was chosen because it is known to influence the release of DEHP (14,21,22,25).

The pump was operated at 200 rpm for 30-minute, 1-hour, and 2-hour trials. Five milliliters of fluid was collected every 10 minutes. Note that the ½″ ID trial began the first sample at 15 minutes. No waste was taken when the samples were drawn. The sample was drawn from high flow stopcocks (26). The fluid was stored in glass vials with screw top lids at room temperature. The samples were kept from light during storage. At the end point, the tubing was weighed and measured. The same process was completed for the ⅜″ ID and the ¼″ ID tubing.

Particle size analysis was accomplished by dynamic light scattering laser technology on the Malvern Zetasizer (Malvern Instruments, Worcestershire, UK). A suitable cuvette held at least 0.75 mL of the test fluid. The carefully handled cuvette was introduced to the sampling port. Particles from <1 nm to 3 µm were analyzed. The volume of the sample occupied by the particles was reported as a percentage.

Analysis of variance was used to determine difference of treatments for time, ID, or wall thickness. Excel was used to generate statistics, graphs, and tables (Microsoft, Redwood, WA).

RESULTS

At 2 hours, all tubing had lengthened by at least 5 mm. The ⅜″ ID tubing lengthened from 18.5″ to 18.8″. This was a percent change of 1.7%. At 60 minutes, the ⅜″ ID tubing had increased by .7%. There was a 1.5% change in length for the ½″ ID tubing after 2 hours. No changes were seen with the 60- or 30-minute ½″ tubing lengths. The same was true for the ¼″ ID tubing. The difference in pre- and post-weight of all tubing segments was negligible.

Figure 3 was the result of a particle measurements for

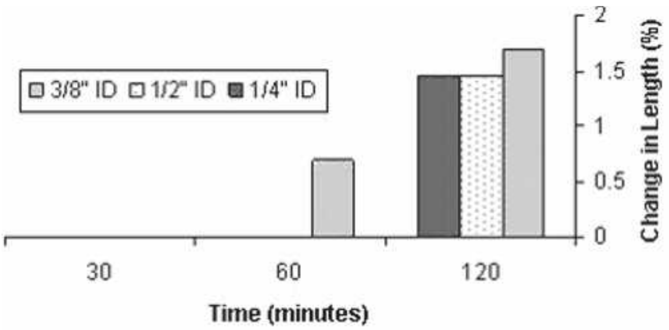

Figure 2. Change in length. The pPVC gained in length over time at all ID. The change in length with respect to time was significant, $p = .001$. The greatest change in length occurred at 2 hours.

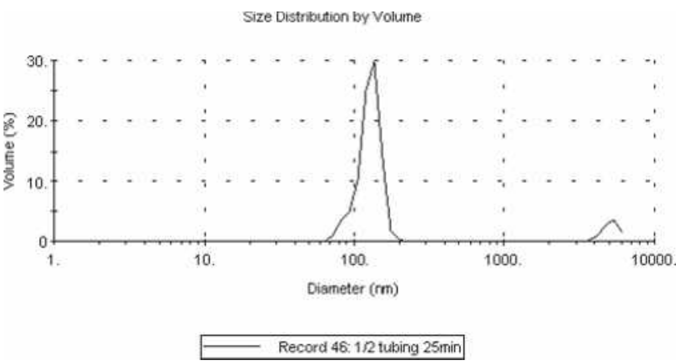

Figure 3. Volume distribution graph. Description of particle volume in prime of ⅜″ ID tubing after exposure to roller head compression. Particles in this example were measured at 100 nm and >1 μm.

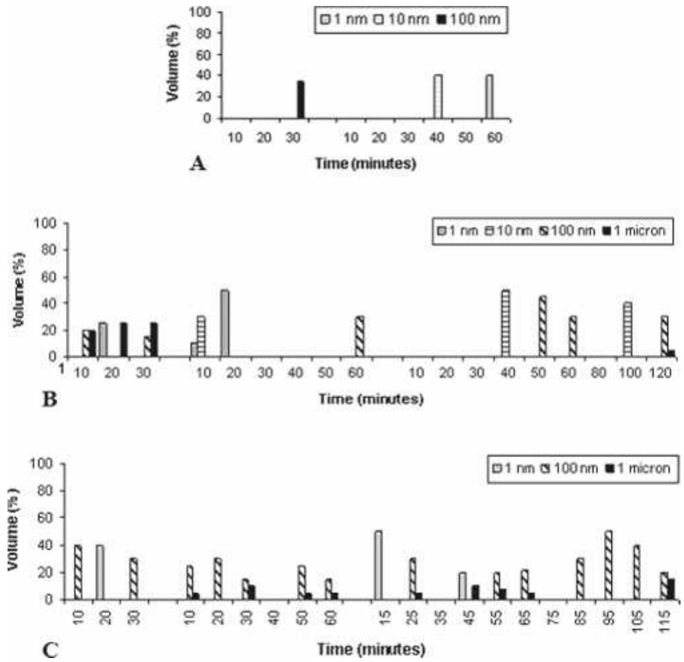

Figure 4. Particle release. All tubing showed particle release. The ½″ tubing registered particles regularly and most consistently. Both the ⅜″ and ½″ segments showed late and early particle release, whereas the ¼″ showed particle release late in the trials. It is believed particle release occurred and equilibrated with the pattern repeating.

each tubing segment for each time point collected. The ¼″ ID samples were limited to 30- and 60-minute trials. Each ID is graphed separately.

Particles measured from 1 nm to >3 μm in volume in all tubing sizes (Figure 4). Figure 3 shows a characteristic plot. Samples were limited to two peaks at most in the volume analysis. There was no consistency of multiple peaks. Particle measurements were not consistent from one 10-minute sample to the next in terms of size or volume.

The particle release occurred in spurts. Small ¼″ ID tubing took longer to release particles. The late release of particles occurred at 30, 40, and 60 minutes. The most consistent release of particles was in the largest diameter tubing. The particle intensity remained measurable throughout all 2 hours. The samples at 35 and 75 minutes did not show peaks.

The ⅜″ tubing released particles early in the 30- and 60-minute trials. This was inconsistent in the 2-hour trial, when particle release did not occur until 40 minutes. Fifteen trials showed .1 μm or larger particles for ½″ ID tubing; nine showed 1 μm or larger particles. Seven trials showed .1 μm release for ⅜″ ID tubing; four showed 1 μm or larger particles.

DISCUSSION

The material properties of the tubing changed during the compression trials. Tubing length increased in a time-dependent response. With continued use for 24 hours, the tubing in this study would have lengthened 2.4 cm, or almost 1 in. Work by Snyder et al. (14) showed changes in length approaching 650% after 21 days with ⅜″ ID tubing. The change in length may indicate changes in the polymer fiber configuration. Length change may represent a loss of elasticity.

The sample preparation showed little change in weight over the course of the treatment. In this study, we expected minimal weight change. Shashoa (1) showed that, at room temperature, DEHP was lost from tubing stored in low-density polyethylene bags at the greatest rate compared with high relative humidity environments. High humidity showed no weight change. Tubing hazed from the humidity because the water was retained (1). In samples left exposed to room air, the greatest loss was discovered in the first several days, with little further ambient loss (1). This is comparable to other DEHP migration studies. In polyethylene glycol–coated pPVC tubes 10% weight loss occurred at 10 hours, leading to a plateau of 30% weight loss at 40 hours (19).

Our previous work has imaged particles on the tubing used in the pump raceway (12). Peek et al. (8) reported

Table 1. Description and size references.

	1 dm	1 cm	1 mm	100 μm	10 μm	1 μm	100 nm	10 nm	1 nm	1 Å
1 m	10^{-1} m	10^{-2} m	10^{-3} m	10^{-4} m	10^{-5} m	10^{-6} m	10^{-7} m	10^{-8} m	10^{-9} m	10^{-10} m
Body	Apple	Wasp	Ant	Hair	Cell	Bacteria	Virus	DNA	Small Molecule	Atom
					<<<<<<<<<<<<<<<<<<<<<<<<Electron Microscope>>>>>>>>>>>>>>>>>>>>>>>>					
<<<<<<<<<<<<<<<<<Human Eye>>>>>>>>>>>>>>>>>										
			<<<<<<<<<<<<<<<Light Microscope>>>>>>>>>>>>>>							

The table shows the ability of different imaging techniques to resolve objects. The particle counter identified the same particles imaged by an electron microscope or light microscope. Particles measured in this study were cell size or smaller. Recreated from Brooks et al. (17).

debris in the raceway in the first hour of roller pump operation. Regardless of the inner or outer wall diameter, in our experience, particles formed within 30 minutes and as early as 10 minutes. During the 30- and 60-minute trials, the ⅜″ ID tubing consistently released particles (Figure 2). At all trials, the ½″ ID tubing showed particle release. Different ID tubing made up each of three treatment groups. There was a significant difference between treatment groups in the 30-minute trial (Figure 2). The other trials trend toward a significant difference between ID. We showed ID influences particle release.

The measurements did not integrate to a larger particle count with time. Some time points did not record a volume (Figure 2). A lack of measurement at any time point in our study was not conclusive of filtering or lack of spallation. Particle release does not have to be consistent and measurable at every time point. More likely, the particle release was diluted by the prime during recirculation.

Studies have shown that the red blood cell is known to deform as it passes through the capillary. The average diameter reduced to just >6 μm (27). There was no indication that the particles released from the tubing changed shape during transit in our circuit. The small particles measured in this study passed through the hollow fiber oxygenator because they shared size characteristics with blood content (Table 1). Large particles, >100 μm, in true microporous membrane pleated oxygenators had been filtered (13,15,28). Hollow fiber oxygenators are not expected to be successful as particle filters. The particles are the size of red blood cells and other prime components. In this study, the particles continued to circulate between samples and most likely dispersed in the solution before the next sample. Sampling from inlet and outlet ports would have provided better comparison and accounted for the circuit components.

We believe that these spalls came from the inner lumen of the tubing consistent with particle imaging of tubing lumen in previous work (7,10,11). Previous images of spalls showed a variety of sizes. For example, Kim and Yoon showed surface dimensions as large as 300 μm (11). Other work has shown surface characteristics and particles as small as 1 μm (10). We measured, by AFM, particles with 10-nm dimensions in a related study (12). Possible artifact in the samples included other non-biological debris of the oxygenator or prime (13).

Wall tension is a calculation of radius and pressure, both directly related. The largest wall tension was in the ½″ tubing under compression. A recent study presented some crack formation from compression from the inside of the lumen progressing out. The final breach completes moving from the outside in. The movement from the outside in progresses toward the initial crack at the time of tubing failure (14).

The ¼″ tubing did not release particles during the first several minutes of roller head use. Less deformation (compressing and expanding) of the tubing was created because the radius of the inner wall was smaller—therefore less wall tension. This may influence why particles were released more readily in the ½″ ID tubing. The ⅜″ ID tubing performed inconsistently, releasing particles early in some trials and late in others. Regardless, ⅜″ ID tubing produced less 1-μm particle measurements.

Shashoua (1) established that tubing with less plasticizer aged faster than more highly plasticized material. Aged tubing changed color, lost volatile plasticizers, and reacted in light to allow polymer chains to become unstable. DEHP at the surface of material protected the material from further degradation (1). DEHP moves from the bulk to the surface by diffusion to maintain surface concentrations. Larger diffusion distance in the 3/32″ walled tubing would have challenged the ability to replenish the plasticizer at the surface. We expect DEHP diffusion in thinner walled tubing protected the pPVC.

This study provided a benefit to appreciating the conditions and properties of tubing under rigorous trials. Tubing compression was deemed to be a real influence in tubing fatigue patterns. Perfusionists must consider tubing inner diameter and wall thickness in choosing the pPVC for the raceway to minimize particulate emboli. This research suggests that ⅜″ tubing produces spalls inconsistently compared with ½″ ID tubing. Thinner wall thickness tubing also has the potential to limit spall formation. Selection criteria of tubing ID and wall thickness for use in a roller pump would benefit from further evaluation.

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