

Long Term Tubing Fatigue Characteristics

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ABSTRACT

The four manufacturers of Polyvinyl chloride tubing were studied with the use of a conventional Travenol roller pump under long term conditions. The conventional roller pump creates spallation, fatigue, erosion, and destruction to Polyvinyl chloride tubing. This is evident with assist time-lapse photography, microscopic examination and observation. All brands are susceptible to fatigue characteristics. Each brand demonstrates forms of fatigue and durations.

INTRODUCTION

The equipment utilized during extracorporeal perfusion has undergone many changes since the early days of heart-lung bypass. The tubing that makes up the extracorporeal circuit has played a significant role in these changes. As early as 1903, Bain discovered that glass and rubber were safe materials for the handling of blood and blood products.¹ Since that time a large number of materials have been tested. In 1959, Stewart and Sturridge found that some types of tubing caused hemolysis of blood.² In 1959-60, Meigler, Durer and Meyler (in separate studies) found that some plastics leaked toxic materials out into the system causing death in laboratory animals,² and in 1968, Haberman, et al., described the harmful effects of protein denaturation by some plastic components.²

Due to the studies of these men, and many others, a standard for the ideal extracorporeal tubing has been established. The ideal tubing has been determined to be one of clear, flexible, non-aging, non-oxidizing, corrosion resistant plastic. It should be non-toxic to blood, non-pyrogenic, easily cleaned and sterilized, produce no tissue reactions and have a smooth inner bore to prevent platelet and fibrin adhesion.^{1,2,4,5,6} With the recent advent of long-term membrane support a new criteria for extracorporeal tubing has been added. The tubing should be resilient enough to retain its shape after several hours of bypass and tough enough to resist "crazing and environmental stress cracking". These are a failure of the polymer under pressure which causes cracking and spallation of particles of plastic into the blood stream.^{7,8}

When we noted obvious scratches and cracking on the outer surface of circuits during long-term bypass, the question of what changes were occurring simultaneously on the inner surface of the circuit, and what pulmonary and neurologic complications could arise from the loosing of microembolic particles of plastic into the circuit. In an attempt

to establish which commercial brand of extracorporeal tubing would be the best for long-term bypass procedures, we began a comparative study of the four most commonly used tubings. The study included: Bentley, Mediflex, Travenol and Norton tubings.

MATERIALS AND METHODS

The four brands of Polyvinyl chloride tubing that underwent this study were manufactured by Norton Plastics and Synthetics, Akron, Ohio, I. D. 3/8 inch, O. D. 9/16 inch; Travenol Laboratory Inc., Morton Grove, Illinois, I. D. 3/8 inch, O. D. 9/16 inch; Bentley Laboratories, Inc., Irvine, California, 3/8 inch I. D., 9/16 inch O. D.; and William Harvey, Santa Ana, California, I. D. 3/8 inch, O. D. 9/16 inch.

A Travenol conventional roller pump was used in each case. A specimen of tubing was inserted in the usual manner, while maintaining sterile technique to avoid any unwanted particles contaminating the lumen of tubing. To complete the circuit, a 3.8 in. by 3.8 in. luer lock straight connector was applied to the end of the tubing, on the positive side of the pump. From the luer lock connector, a light ft. pressure line was attached and a sphygmomanometer was connected to the pressure line for the purpose of monitoring pressure during the study. Attached to the 3/8 in. luer lock was another section of Polyvinyl chloride tubing which linked a William Harvey bypass filter (pore size 40w) or a Millipore filter (type 5m) for the purpose of extracting and collecting any P.V.C. tubing particles which may break off and travel downstream. From the filter, the circuit empties into either a Bentley BOS-10 oxygenator or a William Harvey Adult oxygenator, which was principally used as a reservoir for the collection of fluids which were pumped out through the arterial outlet of the oxygenator. The fluid used to prime the circuit was distilled water with occlusion being checked by holding the tubing, of the positive, up 30 in. above the pump head and increasing the occlusiveness until the fluid level fell at a rate of about 1 cm./min. This was done at the beginning of every run.

At each new insertion of tubing and the onset of pumping, a chart was made out to monitor each study. Flow rates were set and maintained throughout each run. These flow rates ranged from 2000 cc. per min. to 4700 cc. per min. with a mean flow of 3350 cc. per min. Positive side pressures were monitored and ranged from 10 mm Hg. to 220 mm Hg, with a mean pressure of 115 mm Hg. Fluid temperatures at the onset of pumping were at room temperature, but with the fluid in constant motion, plus after several hours of pumping, the Travenol pump head area became extremely warm, which is believed to have some influence on fluid temperatures. Observations were made every 2 to 6 hours, depending on duration of the pump run, and maintained during the critical points, near the end of each run.

Each pump run was halted when the fatigue and destruction of the tubing, resulted in traces of water within the pump head area. At the end of the run, all remaining fluid was passed through the filter existing in the circuit at that time. The tubing was then rinsed with distilled water through the filter. Both were numbered and set to dry.

At completion of the study all filters were examined under a microscope. This was done by applying a mild jet stream of distilled water to the inner wall of the Harvey filters, allowing the water to filter through and settle. Only a small quantity of water remained at the bottom of the filter, which then was drawn up by a clean pipette and inserted into a test tube, to be spun down in a centrifuge at 4000 R.P.M. for 5 minutes. Once again

drawn up by a clean pipette and placed on slides for examination. The millipore filters were done in a similar fashion.

RESULTS

A series of 18 pump runs were done on the four brands of tubing.

Fatigue of polyvinyl chloride tubing can be observed within the first 2 to 4 hours. This abrasion is apparent by small flake-like particles which appear on the exterior surface of the tubing, and in the surrounding area of the pump head. The speed of which this particle formation occurs is in direct relation of the R.P.M. or flow. Flows of 2000 cc per minute to 2700 cc per minute had little or no particle accumulation. Flows above 2700 cc per minute lead to a much more accelerated rate of fatigue and destruction of the tubing, with Travenol P.V.C. tubing leading the four brands in the least amount of resistance to fatigue and destruction. (figure 1, following page)

This abrasion continues through the entire pump run, followed by a change in shape of the P.V.C. tubing. Again, flows of 2000 cc per minute to 2700 cc per minute showed less signs of ovalation of the tube. This event occurred within the first 15 hours. Flows above 2700 cc per min. and 10 to 12 hours into the pump run, would almost seem to lose its flexibility due to the increased number of compressions of the roller head.

Another distinctive feature of P.V.C. tubing at 25 hours to 35 hours, is the cloudy appearance the P.V.C. tubing takes on within that section of tubing in the pump head. Associated with this, in the same time period, are formations of small breaks or cracks which develop, not on the part or side of tubing which comes in contact with the roller head or back plate of the pump, but at the points of maximum flexure, which are located below and above the tubing, as it lies in the pump head. These cracks run horizontal and vertical to the points of flexure and continue to grow with duration.

Near the last ten hours of life of the tubing, the characteristics which have developed early have now grown and are distinct in appearance. In this same time period, if one looks very closely, one can see along the points of maximum flexure, breaks or cracks developing on the interior surface of the tubing. As the exterior develop breaks, so does the interior of the tubing, but these cracks only run horizontally in the same direction as the roller heads itself.

It is only a matter of time, at this late stage of the pump run, that complete breakdown of the tubing is near.

Table One shows the performance of the four brands that were studied.

Microscope examination of the residue on the filters revealed very irregular shaped particles. Some particles appeared to have more of a regular shape, while others were string-like particles.

DISCUSSION

Through this study, one can see that the obvious fate of Polyvinyl chloride tubing, used in a conventional roller pump under long-term durations, is fatigue and destruction of its molecular make-up. Variations may be seen due to flow, which is applied to that tubing at this time. Though the fate of the tubing was the same in each case, and all characteristics were observed, the flow or R.P.M. of the pump was the main factor which

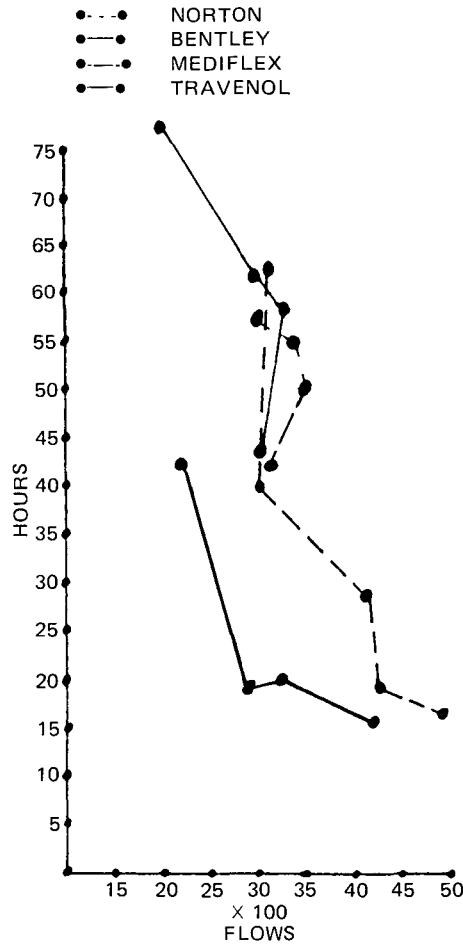


Figure 1.

enables us to step up and change or alter some of the characteristics of the P.V.C. tubing. A good example was the Travenol tubing. When run between 2900 cc per minute and 3500 cc per minute, it displayed numerous cracks all along the point of maximum flexure. If flows were increased above 3500 cc per minute, the cracks appeared in very few numbers, but with an increase in size. This feature was observed in all brands, but Travenol displayed it best. In other words, low flows allowed longer contact of the roller head with the tubing with a more complete breakdown of the entire length of tubing, where

TABLE 1

Flows	Pressure	Duration
Norton:		
3000 cc per min.	10 mm Hg	40 hrs. 16 min.
3200 cc per min.	60 mm Hg	63 hrs. 10 min.
4008 cc per min.	130 mm Hg	28 hrs. 10 min.
4056 cc per min.	10 mm Hg	18 hrs. 35 min.
4710 cc per min.	152 mm Hg	16 hrs. 20 min.
Bentley:		
2000 cc per min.	220 mm Hg	77 hrs. 6 min.
3000 cc per min.	60 mm Hg	61 hrs. 5 min.
3000 cc per min.	55 mm Hg	43 hrs. 55 min.
3300 cc per min.	75 mm Hg	57 hrs. 10 min.
Mediflex:		
3000 cc per min.	30 mm Hg	43 hrs. 20 min.
3100 cc per min.	37 mm Hg	57 hrs. 2 min.
3200 cc per min.	200 mm Hg	55 hrs. 25 min.
3500 cc per min.	60 mm Hg	51 hrs. 35 min.
Travenol:		
2340 cc per min.	45 mm Hg	42 hrs. 45 min.
2900 cc per min.	40 mm Hg	19 hrs. 20 min.
3275 cc per min.	110 mm Hg	20 hrs. 35 min.
4212 cc per min.	110 mm Hg	16 hrs. 15 min.

All pumping was stopped at first signs of water within the pump head area.

as an increase in R.P.M.'s allowed less contact, but in greater numbers, causing greater destruction.

The microscopic examination obtained from the filters, suggest that these particles were generated by the pump, and emboli abrade from internal surfaces of Polyvinyl chloride tubing were created by the compression at the point of maximum flexure.

Hodge and Leverett conducted a similar study of P.V.C. tubing, in which particles were produced by the pump within the first hour of operation, with flows of 4 liters per minute. Particles size ranged up to 1.2 mm in dimension.

John W. Boretos and Frank R. Wagner, conducted a study on Polyurethane tubing, and found it produced fragmentation, but of a lesser degree.

Microscopic examination of the internal surface of an unused portion of P.V.C. tubing revealed a clear, transparent field with only small lines, which are formed from the extrusion process during development of the tubing. This same tubing was examined after being run for 20 hours, 55 minutes, at a flow rate of 3275 cc per minute, in a conventional roller pump. Upon examination, one could see along the point of flexure, large amounts of microscopic cracking, which suggests the possibility that if the tubing had continued, the areas of examinations would have been probable sites of fragmentation, generated by the pump.

One would have to ask the probability of damage that might occur due to the accumulation of these particles in an organ.

CONCLUSION

At the present time, the tubing for extracorporeal circulation apparatus is designed for the duration of time of a normal heart-lung bypass procedure. The extra demands of resilience and endurance placed on the tubing by long-term membrane support has prompted a comparison of various companies for the longest lasting extracorporeal tubing. The ideal tubing should be translucent, flexible, non-wettable, non-pyrogenic, non-oxidizing, have a smooth inner bore and be physically tough. Several consecutive hours of pressure from the roller pump heads should not cause tubing fatigue and breakdown.

In our study, we found a directly proportional increase in tubing fatigue with an increase in flow rate (liters/min) at the same occlusion. As breakdown became evident on the exterior of the extracorporeal tubing, a similar breakdown was found on the interior surface of the tubing. The spellation of microemboli was found on examination of in-line filters and microscopic examination of the tubing itself. Individual perfusionists should keep in mind not only the inconvenience produced by tubing fatigue but also the potential pulmonary and neurologic hazards to the patient of microembolic plastic particles being released from the inner surface by extracorporeal tubing and entering the bloodstream.

As a result of our study, we highly recommend the frequent observation by the perfusionist of the bypass circuit and changing or rotation of worn tubing at the earliest sign of internal cracking. The use of an in-line arterial filter is also recommended.

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