

Original Article

Investigation of Fatigue Failure of S-65-HL "Super Tygon" Roller Pump Tubing

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ABSTRACT

A failure analysis was performed on Norton S-65-HL Tygon[®] tubing. Fatigue testing was performed on four sizes of this tubing, and essentially showed *how* the tubing wears out. A dynamic "life hours to failure" test, which was performed on the 3/8" internal diameter (ID) size, quantified *when* the tubing ruptured. Based on results of laboratory testing and the institution's clinical extracorporeal membrane oxygenation (ECMO) experience, a reasonable life expectancy for the 3/8" S-65-HL Tygon[®] size was determined for use in this institution's neonatal ECMO system.

An understanding of the expected performance of roller pump tubing - an integral component of the ECMO system - is imperative to providing safe, effective extracorporeal life support.

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INTRODUCTION

Roller pump raceway tubing (Figure 1) is subjected to the most stress and strain of all tubing used in an extracorporeal circuit (Figure 2). Strain (fractional deformation) of the tubing is caused by the compressive stress (or force per unit area) imparted to the tubing by the pump rollers. The damaging forces that are applied to the tubing are shown in Figure 3. Anecdotal and published reports of roller pump tubing rupture identify air embolism as a known complication of ECMO (1). Literature of the Extracorporeal Life Support Organization (ELSO) describes the potentially fatal effects of "raceway rupture," with blood loss and air emboli complications (2). According to the ELSO Registry, the incidence of mechanical complications (which include raceway rupture) related to ECMO have significantly increased from the 1973-1988 period (0.27 per case) to the 1990-1992 period (0.75 per case) (3). With regard to the most common perfusion problems encountered in general cardiopulmonary bypass, gas embolism has been identified as the third leading cause of morbidity and mortality (4).

From a historical perspective, the risk of tubing rupture may have been reduced by having ECMO practitioners routinely "walk" (or advance) a new section of tubing through the roller head at regular intervals. The purpose was to avoid continuous stress on the same raceway tubing section by not allowing the rollers to continually contact one area (5). Norton^a S-65-HL polyvinylchloride (PVC) tubing, nicknamed "super Tygon" (ST) by its users (6), is currently the tubing of choice for neonatal ECMO (7). ST is formulated to have "two and one half times the life of [Norton's standard] S-50-HL" tubing (8), and extant ECMO literature implies that the problem of raceway rupture is "...now averted with the use of the more durable PVC tubing ('Supertygon'®...)" (9). Norton's literature, though, states, "As we all know, no tubing will last forever..." (6).

Using ST can reduce, but does not necessarily eliminate, the possibility of catastrophic results stemming from tubing rupture. This belief is echoed by Norton in an informational sheet that the company has recently published. (The authors noticed that this sheet, entitled "Tubing Hazard Warnings & Use Instructions," began appearing in ECMO tubing packs assembled in early 1995 by at least one supplier.) Even if ST is more durable than S-50-HL tubing, its use still requires a certain amount of discretion. Tubing may last for a stated length of time under one user's conditions, but general conclusions as to the performance of the tubing are dif-

ficult to draw since all ECMO centers subject the tubing to different conditions. The most misleading assumptions are those that people are not even aware they are making. Usage variables (Table 1) include the tubing itself, roller pump type, occlusion setting and procedures for walking the raceway (5).

In order to help establish guidelines for the safe use of ST in this institution's newly-purchased Multiflow^b roller pumps, a failure analysis of ST tubing was performed. Fatigue and "life hours to failure" tests were initially performed on 3/8" ID (3/32" wall thickness) ST tubing, since this was the size originally used with the institution's S10KII^c roller pumps. The investigators realized that because the Multiflow pump has a five inch roller head, in contrast to the S10KII's four inch head, tubing

Figure 1: Tubing in roller pump head; inlet and outlet arrows indicate blood flow

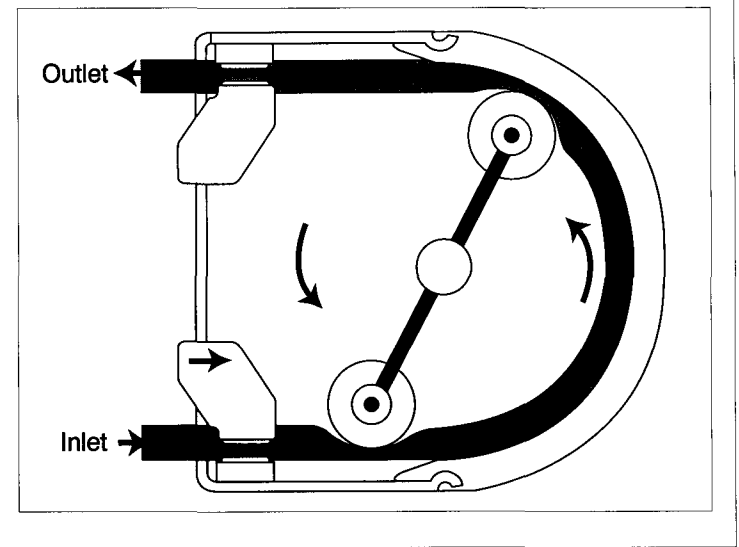
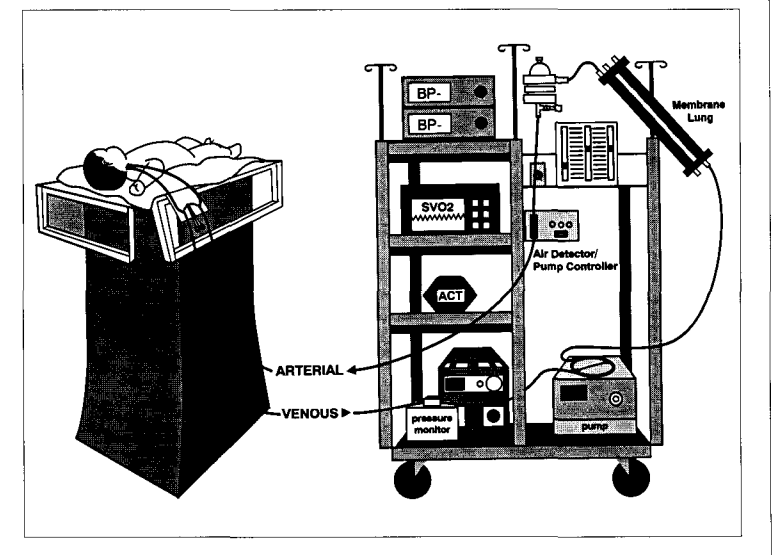


Figure 2: Thomas Jefferson University Hospital neonatal ECMO system



a Norton Performance Plastics Corporation, Akron, Oh 44309
 b Sorin Biomedical, Inc., Irvine, CA 92713
 c Sarns 3M Health Care, Ann Arbor, MI 48106

would undergo a different number of occlusions per minute to achieve the same flow rate. Hence, the tubing would wear differently. The purpose of the proposed tests was to demonstrate how tubing fatigues and when it fails to effectively pump fluid under specific conditions. Since 3/8" ST is not universally used in neonatal ECMO (9), three other commonly available sizes were tested to see if progressive deterioration (tubing fatigue) was uniform in all sizes. It was thought that possibly one of these sizes might more closely fit the institution's needs.

At the time this study was done (late 1992), Norton offered no guidelines regarding the applications of ST, beyond suggesting it for use in neonatal ECMO (10). Although in-vivo and in-vitro testing of ST had been published by independent researchers (11), the tubing tested by these researchers was not 3/8" and it was performed under conditions different from Norton's. In data published by Norton on ST tubing (related to the 3/8" size), a life hours to failure figure of 133 is specified (8). It is unclear whether this is an average value and if any variation would be expected if a different blood pump was used (Norton used a Sarns model 6002 in its testing). Conditions are published under which testing was performed, but other questions piqued the authors' clinical curiosity. Does "partial occlusion" mean the same thing to all people and would Sarns' procedure for setting occlusion affect the tubing differently than Sorin's method? Does "failure," in Norton's terms, account for gross spallation or does it mean an actual tubing rupture that prevents effective pumping of fluid? Can one apply results attained under high-flow conditions (4.5 L/min) to low-flow neonatal use? These are quality assurance issues that an institution can address through laboratory testing with its own ECMO system.

MATERIALS AND METHODS

The purpose of the testing was to strictly monitor tubing deterioration under the simplest conditions possible (in order to minimize the effect of variables in the global clinical ECMO environment). Initially, tubing deterioration by a roller pump was determined and aspects of the tubing's changing dimensions and physical properties with use, was quantified. Then "Life Hours to Failure" testing was done on the 3/8" ST to determine when this tubing would actually rupture based on conditions published by Norton. The authors were interested in the performance of this specific size because it was the one that the institution had the most clinical experience with.

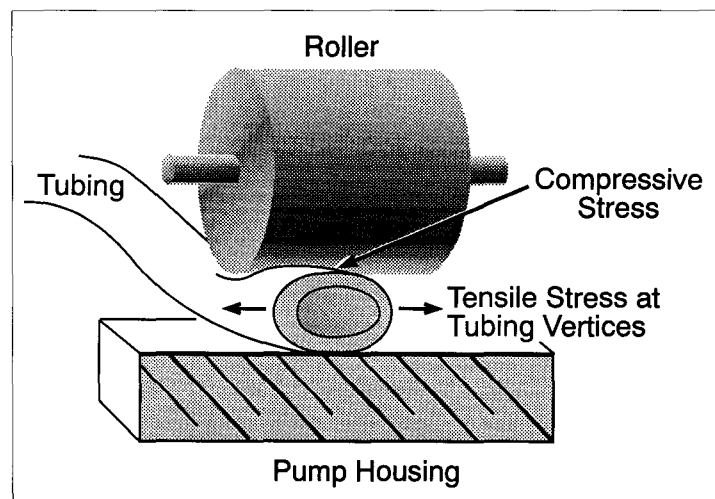
Fatigue. Fatigue tests were performed to measure how the tubing material withstands an applied stress under cyclic loading. Four sizes of non-sterile ST were used in the Sorin pump and later analyzed: (internal diameter X wall thickness) 1/4" X 1/16", 1/4" X 3/32", 3/8" X 3/32", and 1/2" X 3/32". Each size was cut from a continuous roll (same lot number). The laboratory ap-

paratus consisted of a closed-loop of water-filled tubing with 500 mmHg back pressure. RPM was set at 20, which corresponds to a flowrate of 450 ml/min through 3/8" tubing (flowrate through the 1/4" tubing was approximately half of this since the ID is half the size). Occlusion was set for the specific tubing sizes according to Sorin's specifications (2.5 centimeter drop in water column over one minute, from a height of 75 cm above pump head [12]). Three separate trials (of each tubing size) lasting 7, 14, and 21 days were conducted; position of tubing was not changed after initial placement in the pump head. Four samples of each size tubing were analyzed at the conclusion of each trial (one was an unused segment for reference). For example, tensile strength analysis involved four separate sections (18 inches long) of 3/8" ST. One sample was new, one was run in the roller pump 7 days, one for 14 days, and one for 21 days. All four tubing sizes were tested.

Analyses were carried out by Drexel University Department of Materials Engineering (Philadelphia, PA), according to American Standard Testing Method (ATSM) D-876-80. Tensile strength, modulus, and elongation testing were performed on these tubing samples.

Dimensional Changes. The purpose of this analysis was to examine tubing for signs of visible wear, including changes in wall thickness. Sections of tubing 1.5 centimeter in length were cut from the tube and mounted in an epoxy holder so the cross-section of the tube wasn't covered with epoxy. When the epoxy hardened, the holder with the tube section was placed into a sputtering chamber to sputter thin gold film on the cross-sectional surface. After gold sputtering, the tube cross-sections were analyzed using scanning electron microscopy. The thickness of the tube walls was measured with 1 μm resolution using micrographs of the tube cross sections. The development of the fatigue crack at the tube's vertices was also studied.

Figure 3: Various stresses to tubing caused by roller action in pump



Physical Properties. To quantify changes in tensile strength, modulus, and elongation, an Instron^d 1127 universal testing machine was used. Dumbbell-shaped samples 50mm long and 20mm wide, with a neck of 4mm, were cut from the tubing.

Tensile Strength. Tensile strength is a mechanical property of a material that shows how much force can be applied to that material before it breaks. It is defined as the force per unit area of the original cross sectional area which is applied at the time of rupture, expressed in pounds per square inch (psi) (13). Tensile strength of the specimen was calculated as follows:

$$\text{Tensile Strength} = \frac{\text{Load at break (Lb)}}{\text{cross-sectional area for dumbbell-shape (in}^2\text{)}}$$

Elongation. The term elongation is used to describe the amount that the specimen stretches before fracture. It is defined as the extension between the jaws produced by tensile force applied to a specimen and is expressed as a percentage of the original distance between the jaws. Elongation at break is the elongation at the moment of rupture. In other words, the elongation at break is expressed as the percent elongation of the original bench mark length attained at the moment of rupture.

$$\text{Percent Elongation} = \frac{L-L_0}{L_0} \times 100$$

where L is the length of the sample at the moment of rupture, and L₀ is the distance between the jaws, i.e., the neck length of the dumbbell-shaped part.

Figure 4: Tubing fatigue, 7 days (minimal visible wear)

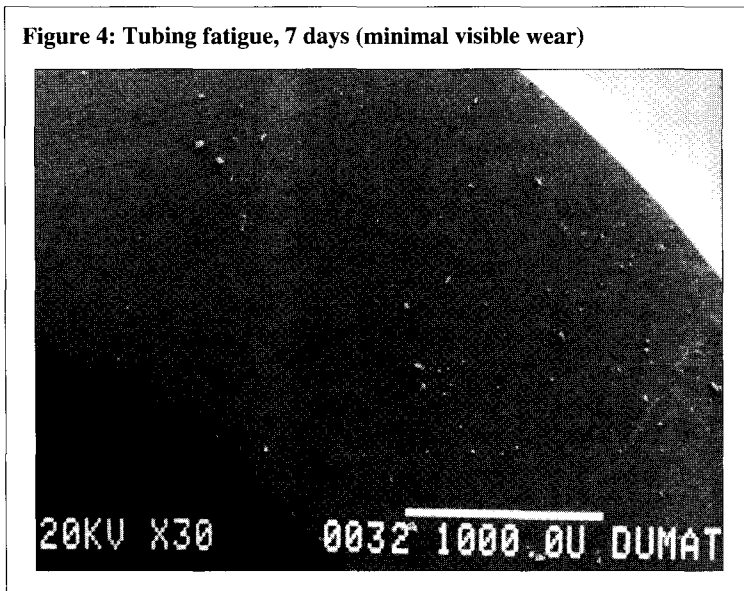
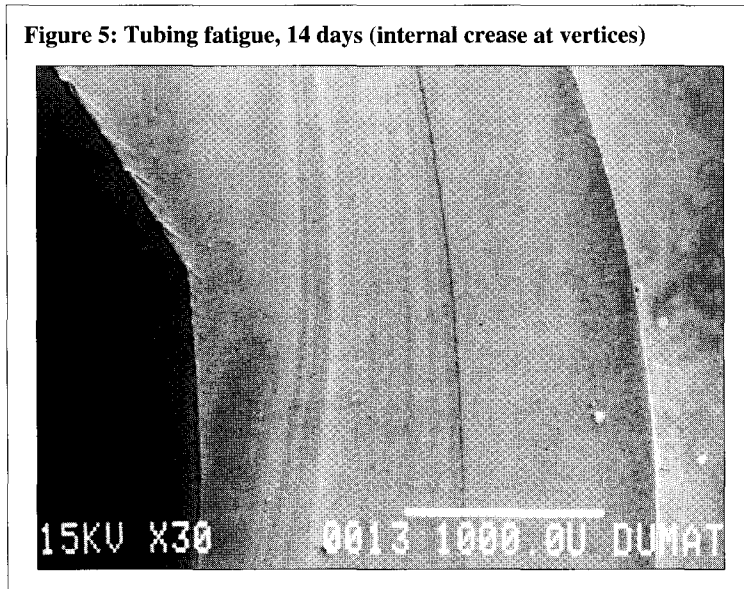


Figure 5: Tubing fatigue, 14 days (internal crease at vertices)



Modulus. Modulus is a measure of the stiffness of the material. It is a constant of proportionality between stress and strain (stress = modulus x strain). This “elastic limit” of a rubber specimen is defined as the force per unit area of the original cross-sectional area required to stretch the specimen to stated elongation. In this work, the modulus at 25% elongation was measured and expressed in psi. Higher modulus means that the material maintains its shape even under an elastic load.

Life Hours to Failure. For the life hours to failure testing, 20 samples of non-sterile 3/8" ST (Lot #037030622) were run to rupture (fluid leak) in the Sorin pump under conditions similar to those published by Norton (4). Attempting to duplicate Norton's results seemed a good starting point from which to proceed with further investigation.

Distilled water at 30°C was run through a closed loop of tubing, through an Avecor^e RV-500-1 one liter reservoir. The pump was set at 170 RPM, corresponding to a flowrate of 4.5 L/min through 3/8" tubing. Occlusion was set for this tubing size according to Sorin's specifications; position of tubing was not changed after initial placement in the pump head. Back pressure was maintained at 500 mmHg. Hours and number of occlusions to failure were noted for each sample.

RESULTS

Fatigue. Measurement of the mechanical properties of ST was carried out as a function of tube diameter, thickness, and days in use. In the process of this study, fatigue caused by roller action on four sizes of ST tubing was quantified. In the three trials of 7, 14, and 21 days, no tubing

^d Instron, Canton, MA 02021
^e Avecor Cardiovascular, Inc., Plymouth, MN 55441

Figure 6: Tubing fatigue, 21 days (crease progressed to become a fissure)

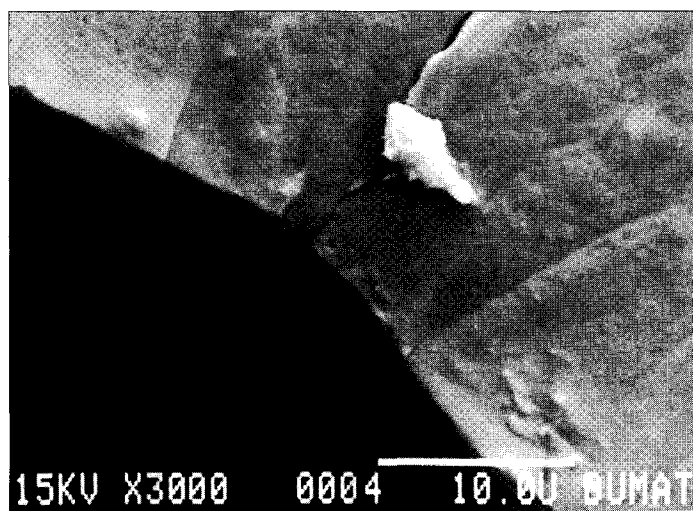
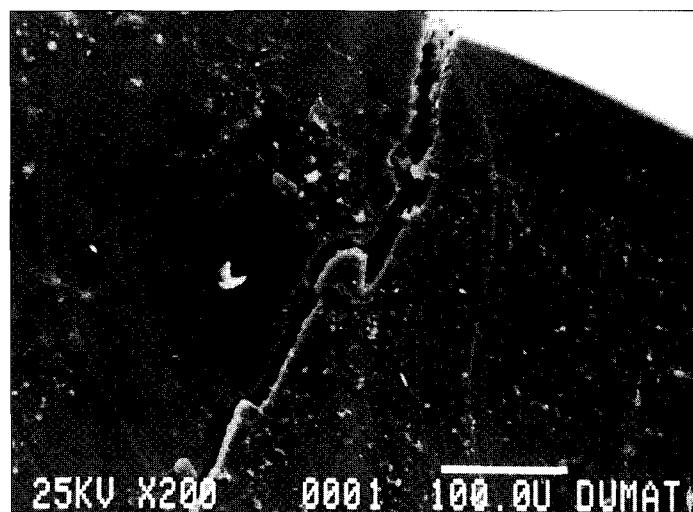


Figure 7: Tubing fatigue, external crack progressing toward tubing lumen

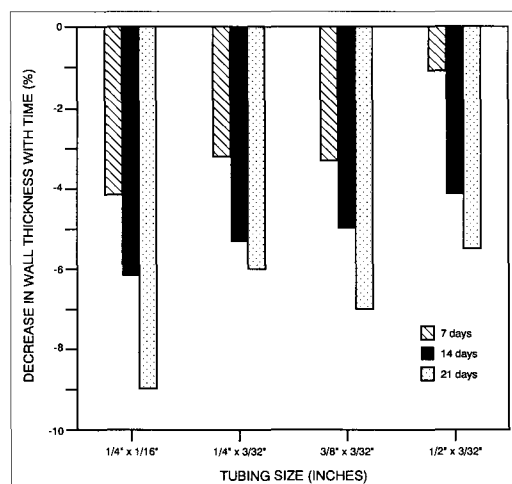


rupture occurred. Tubing fatigue progressed through these stages:

1. Minimal visible wear (Figure 4)
2. Scuff marks and abrasions on tubing exterior
3. Deformation of the round cross sectional shape to an ellipse with a crease at the vertices (Figure 5)
4. Thinning of wall in fatigued area
5. Internal crease or groove becomes a fissure (Figure 6)

Internal cracking progressed in the crease areas but no fluid leak occurred by 21 days. The progression from normal to excessive wear was obvious in all samples and sizes and is shown in Figures 4-7. All tubing sizes exhibited similar progressive

Figure 8: Decrease in tubing wall thickness with use



deterioration. Laboratory results regarding the 3/8" tubing paralleled clinical experience at this institution, in that creasing at the elliptical vertices appeared by day 10.

Dimensional Changes. Figure 8 shows that the tubing wall thickness (at vertices) decreases as it fatigues in a roller pump. Each tube section subjected to the roller pumping showed a notch developing over time with pumping. This notch is the origin of the fatigue crack, which begins on the inner wall and propagates toward the outer wall. The thickness of the tube wall was measured every time in the vicinity of this notch, which made the experimental data reproducible. Thickness decreased with pumping time. The change of tube wall thickness with relation to use in the roller pump is shown in Figure 8. The 1/4" X 1/16" tubing experienced the maximum decrease in thickness of any size - its diameter decreased 9.1% after 21 days of pumping. The thicker the tube wall, the smaller was the measured reduction in thickness for the same period of pumping.

Physical Properties: Tensile Strength. Figure 9 shows the change in tensile strength of ST as a function of tube diameter and thickness. Generally, the tensile strengths of all four sizes of ST samples do not differ significantly from the manufacturer's published value (2400 psi). As time in service increases, the tensile strength generally decreases, albeit slowly.

Modulus. Figure 10 shows the effect of roller pump use on modulus for the four sizes of tubing. It was found that the modulus decreased as time in service increased for all sizes of ST. Since stress = modulus x strain, the elastic limit of the material decreases with use. Figure 10 also shows that 1/4" X 1/16" ST is more elastic than the other sizes tested.

Elongation. Ultimate elongation of ST varied with thick-

ness. The ultimate elongation of 1/4" X 1/16" and 3/8" X 3/32" increased with time in service. Figure 11 shows the effect of roller pump use on ultimate elongation.

Life Hours to Failure. While fatigue testing showed how tubing wore out, life hours to failure showed when the tubing ultimately failed to effectively pump fluid.

Twenty samples of 3/8" ST were run to rupture (Figure 12). Based on these laboratory tests, 320 hours (approximately 13 days) is the mean life hours to failure of 3/8" ST when using it in the Sorin pump, at a flow rate of 4.5 L/min under test conditions previously described. Life hours to failure actually ranged from 58.5 to 657.5 hours, or approximately 2.4 to 27.4 days. Mean number of occlusions to failure was 6,528,000 (320 hours x 340 occlusions per minute, at 170 RPM).

In the life hours to failure testing, tubing cracks always progressed from the crease line (the elliptical vertices of the inner wall), toward the outer wall of the tubing. Some time after 14 days, all samples of 3/8" ST under test began to develop an external crack at the crease line. Rupture which actually allowed fluid leak during in vitro testing always occurred after a crack began on the outside of the tubing. The exterior surface crack propagated through the PVC due to the cyclic compression and non-uniform tensile stress at the tubing vertices caused by the rollers.

DISCUSSION

The probability of mechanical failure of ST tubing increases as time in service increases, since the material's physical properties are adversely affected. As tubing fatigues in a roller pump, wall thickness decreases. Tensile strength generally decreases, which would suggest that the material becomes weaker and will eventually break under the applied forces (slight increases may be related to varying degrees of molded-in stress left during the manufacturing process and/or as polymer chains are re-oriented as the tubing fatigues). Progressive deterioration suggested by the modulus results show that, with use, the tubing is less likely to return to its original shape when an applied stress is removed. An increase in elongation with time in service may indicate greater elasticity (the degree to which the tubing material will deform under load, without breaking). The general message, however, is that with use, the tubing literally wears thin, loses strength, and is more likely to rupture than when it was first placed in service.

For a variety of reasons - not the least of which was the fact

Figure 9: Tensile strength change with use

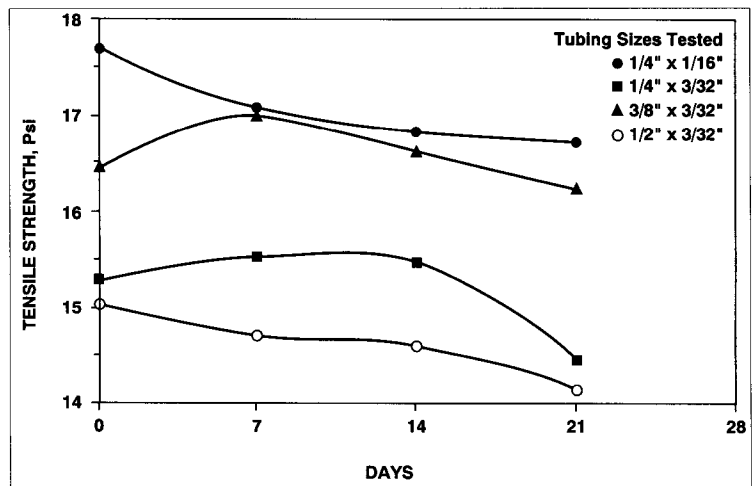
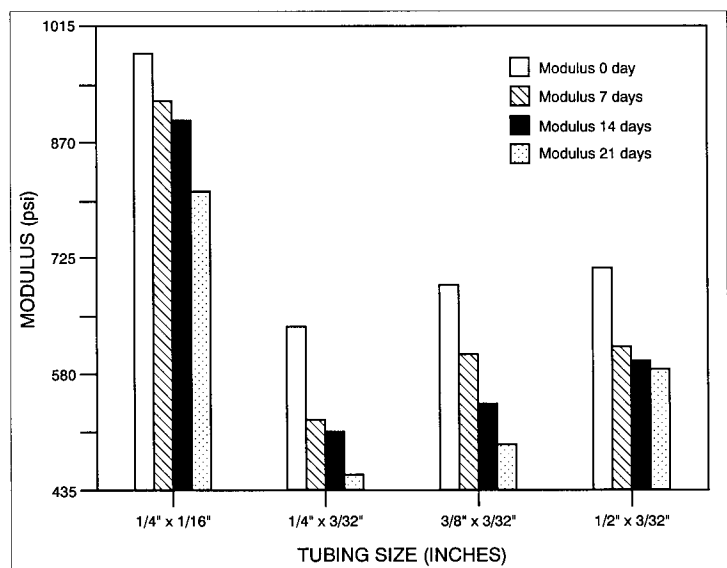


Figure 10: Modulus change with use



that this institution had a few years of clinical experience with 3/8" ST - it was decided to conduct further tests on this size for use in the institution's ECMO system. Fatigue test results showed that 3/8" ST exhibited minimal wall-thinning with use, had relatively high tensile strength, and showed good durability (modulus) and flexibility (elongation). None of the three samples of 3/8" ST showed cracks by day 14 or leaks by day 21 in the fatigue tests that were performed. It should be noted that these results differ from the results of life hours to failure testing mainly due to the number of occlusions the tubing experienced. Fatigue testing showed how tubing progressively deteriorated under low speed pumping conditions. Life hours to failure, which showed when the tubing ruptured, was quantified at a much higher pump

speed (simulating Norton's test conditions).

Tubing will withstand a finite number of occlusions (or impacts) before it ruptures. The number of occlusions is directly influenced by RPM (longer support times or bigger patients) and pump head size. All things being equal, the higher the RPM, the faster the tubing will fatigue. In one study, a higher incidence of raceway ruptures of ST was found in ECMO patients requiring pump flow rates greater than 1,000 ml/min (1). The information regarding variability of ST performance may be of more value to those institutions performing higher flow pediatric and adult ECMO than for those doing neonatal ECMO.

The most commonly used pump tubing in neonatal ECMO is 1/4" X 1/16" ST (14). While the authors found this size to have high modulus and good flexibility, its wall thickness decreased more quickly with use than that of other sizes tested.

Life expectancy for 1/4" ID tubing (of either wall thickness) in the Sorin pump could be half that of 3/8", if based solely on number of occlusions. Since RPM must be doubled to achieve the same flowrate as 3/8" would allow, this would double the number of occlusions imparted to the tubing. A length of tubing will withstand a finite number of occlusions before it ruptures. This rationale was used to eliminate 1/4" ST from further consideration. Although 1/2" tubing would require a lower RPM than 3/8" to achieve the same flow rate, it would be difficult to control blood flow with any roller pump at such a low speed setting. Therefore, 1/2" ST was also eliminated.

Many determinants of raceway tubing life are listed in Table 1. The type of tubing (whether it be ST or any generic PVC, urethane, silastic, etc.), its physical properties, and its dimensions (including manufacturing composition and allowable variances), all affect the tubing's performance. Back pressure (caused by patient, oxygenator, or anything else that provides resistance to blood flow on the arterial side of the ECMO circuit) affects the tubing in the ECMO system. Blood temperature and chemistry may affect tubing physical properties. Various types of sterilization weaken PVC's molecular bonds, and resterilization is usually not recommended by tubing manufacturers. Tubing should be examined before and during use for defects caused by manufacturer, assembler, or end user. Since pump raceway housing abrasions can deteriorate tubing externally, this should be checked periodically by a competent biomedical equipment technician, as part of

Figure 11: Elongation change with use

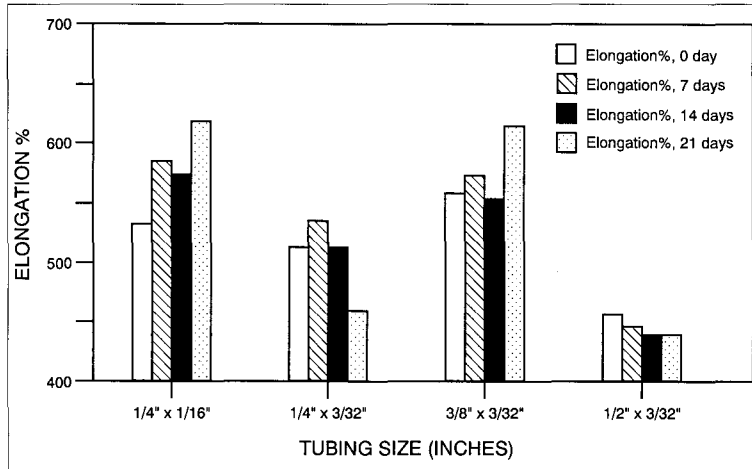


Figure 12: Results of "Life Hours to Failure" testing of 3/8" Norton S-65-HL ("super" Tygon) pump tubing

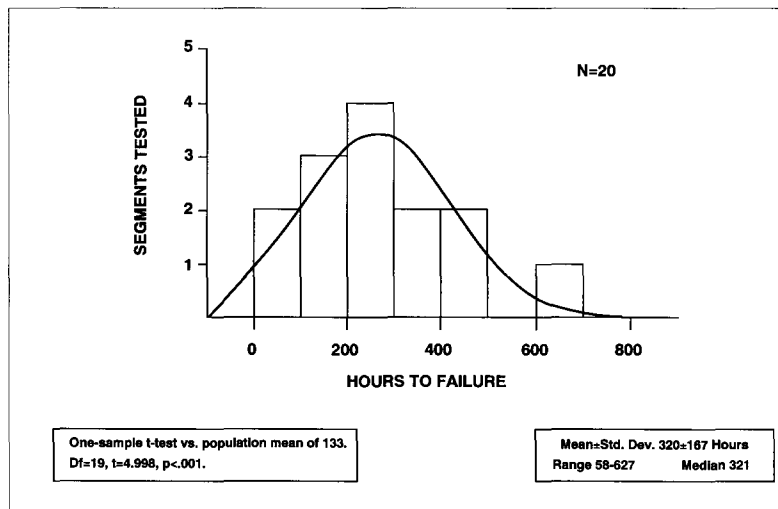


Table 1: Variables affecting life of roller pump tubing

1. **PUMP DESIGN** (manufacturer, model, etc.)
2. **RPM/FLOW RATE**
3. **TUBING PROPERTIES** (material type, dimensions, normal manufacturing variations, defects)
4. **OCCCLUSION SETTING**
5. **NUMBER OF OCCCLUSIONS**
6. **BACK PRESSURE** (caused by patient and arterial line components)
7. **RACEWAY HOUSING ABRASIONS**
8. **STERILIZATION PROCESS**
9. **FLUID TYPE AND TEMPERATURE**
10. **RACEWAY "WALKING" PROTOCOL** (technique, frequency, etc.)
11. **TUBING INSTALLATION IN RACEWAY** (twisted or kinked, excess lengths)

the routine system integrity and performance inspection. A proper and consistent method of setting roller occlusion and placement of tubing in the pump head must be followed (see pump manufacturer's operator's manual) in order to reduce the risk of hemolysis and tubing damage. Overocclusion, which applies unnecessary stress to the tubing, may be caused by incorrect adjustment of rollers or frozen roller bearings.

In the laboratory, spallation and internal cracking developed many days before an external crack was evident. However, since severe internal damage to roller pump tubing occurs much earlier than obvious external cracking, gauging tubing life by external appearance is simply an unsafe practice. Since an external crack is indicative of imminent rupture (given the results of this study), immediate user intervention (raceway walking, tubing splice, circuit change, etc.) should occur if an external crack appears. As tubing rupture always occurred at the outlet (high pressure side) of the pump segment (during *in vitro* testing), it would appear prudent to walk tubing through the pump head so that the worn segment is always on the low pressure (venous) side of the blood pump.

Clinically, this institution has never observed significant external tubing wear to the point of cracking. Samples of pump segment tubing from random clinical ECMO cases are visually examined after termination of ECMO treatment as part of ECMO quality assurance. Although clinical runs lasting up to 14 days (without walking the pump segment) at this institution have never resulted in tubing rupture, awareness of the determinants of tubing wear have prompted periodic reevaluation of the "walking" protocol. Determining the practical end of the pump segment's useful life, however, is a difficult issue. Life hours to failure end-point type analysis is obviously not the only relevant factor in determining useful life. For example, when the tubing wall thins out with use, not only is the tubing material weakened, but the effective occlusion changes, resulting in decreased flowrate even though pump RPM hasn't changed. Also, at some point in the fatigue process, spallation (detachment and fragmentation of tubing material at the tubing/fluid interface) begins and continues during repeated compression by the rollers. This can result in microembolism of particles into the blood (1). Additional investigation is necessary to determine useful life of pump tubing, which would necessarily take into account such related issues as spallation and arterial line filtration of particulates in long-term bypass (15).

At the time this research was conducted, Norton's published value for life hours to failure was 133. If this is a mean value, then there is disparity between 133 and 320, the value reported by the authors of this paper. Both sets of data are only estimates, and may not be authoritative. There are several possible reasons for the difference between the life hours to failure number of 320 arrived at in this testing and that published by Norton. Sample size may have differed, as perhaps did many of the variables listed in Table 1. But since so many variables were held constant in the authors' testing, why was there so much variability in the data? Assuming that the authors' experimental con-

ditions were similar to Norton's, a factor that could contribute to the great variability in the data is the tubing itself. In the present study, a sample size of 20 is probably too small to draw conclusions as to whether early failures should be considered in order to completely avoid a rupture event.

If mean life hours to failure of 3/8" ST is 320 hours (about 13 days) with the described test apparatus at a flow rate of 4.5 L/min (170 RPM), then it is tempting to assume that at a neonatal ECMO flow rate of 350 ml/min (14 RPM), the tubing should last at least that long. The fact is, testing must be done at this lower flow rate to determine the expectations of tubing life under these conditions. Had the data from the 3/8" life hours to failure not been so variable, lower speed testing would have been done by these investigators to more closely simulate neonatal ECMO conditions. Questions raised by the data presented in this paper strongly suggest that more research is needed in the area of raceway tubing performance. If this institution had not had clinical experience with ST prior to this testing, it would have been difficult to determine expectations of tubing life from fatigue and life hours to failure test results alone. Based on the aggregate experience with hundreds of neonatal ECMO cases done at this institution using ST tubing and results of the testing described in this paper, the institution was in a better position to make an informed decision regarding the continued use of 3/8" ST in its neonatal ECMO systems.

Under current usage conditions at this institution, it was felt that 3/8" x 3/32" ST would offer the best performance of the four sizes studied, on the condition that strict guidelines be followed. These guidelines account for variables in the clinical ECMO environment that have been identified at this institution. The following preventive measures have been identified by the authors to ensure safe use of ST in an effort to reduce the risk of perfusion accidents related to raceway rupture at this institution:

- Walk the raceway every ten days, with movement of tubing in the direction opposite blood flow (so that worn segment is always walked to the low pressure, i.e. venous, side of the blood pump).
- Continue adhering to pump manufacturer's guidelines for setting roller occlusion.
- Continue to employ air detector/pump controller system (16) (Figure 2) and heat exchanger with air trap to provide an additional level of patient safety in the ECMO system.
- Continue routine visual inspection of the pump tubing segment by the ECMO Nurse Specialist for signs of wear.
- In addition to preventive measures, continue to practice treatment protocols such as debubbling and splicing tubing. These skills are maintained by ECMO Nurse Specialists through emergency water drills and other wet lab training.

CONCLUSION

Super Tygon® is a welcome technological advancement in roller pump tubing with applications in prolonged extracorpo-

real life support. Despite the generally positive experience with this tubing in neonatal ECMO (approximately 300 neonates treated at this institution utilizing ST), the reality is that any tubing will rupture once it is fatigued enough by a roller pump. Super Tygon® is not indestructible. This research will hopefully raise the level of user awareness regarding this issue.

An effective method of decreasing the risk of patient injury during ECMO is to practice techniques and evaluate new devices in the laboratory before trying them clinically (17). Risk-minimizing protocols for dealing with life-threatening complications are in place at this institution in anticipation of the known risks.

It is acknowledged that testing the tubing in the manner described in this paper did not account for or attempt to control the many variables to which raceway tubing may be exposed in ECMO (Table 1). The purpose of the study was to acquire data under controlled conditions related to tubing deterioration. This data was used along with clinical ECMO experience to establish safe guidelines for the use of ST under this institution's specific conditions. The intent was not to establish an industry or hospital standard. This work should be considered as a suggested framework for future research and should not stand so much on facts presented as on research yet to be done, research suggested by questions raised in and by this paper.

While neonatal ECMO is a standard of care, many specifics of how it is done are not. Since conditions (e.g. devices and techniques) vary among ECMO centers, the way in which ST is used cannot be standardized. Attempts are being made, however, by ELSO, to at least identify differences and communicate them to member institutions (7, 16, 18). Drawing parallels, then, from this work to ECMO systems at other institutions may be inappropriate; ST will unequivocally perform differently under different conditions. The present work should be considered as a suggested program or framework for future research. For example, the life hours to failure test process described in this paper can be used for analyzing the performance of tubing in any roller pump driven ECMO system.

To get a clear picture of how tubing will wear in a specific roller pump, the tubing should be tested in that pump, with rollers occluded the way they will normally be occluded clinically. Closely approximating the clinical conditions to which the tubing will be subjected should enable the user to arrive at a reasonable expectation of raceway tubing life expectancy.

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