Comparison Study of Connector and Tubing Blow-Off Line Pressures

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Abstract

The purpose of this study is to compare the blow-off pressure of a selection of connectors, tubing and tubing attachment techniques currently available for construction of extracorporeal circuits.

Each connector and tubing combination was filled with H₂O and sealed at both ends. Hydrostatic pressure was increased, through a luer side port, until a pressure drop indicated connection failure. Line pressure, P.S.I., was measured with a hydrostatic gauge through a second luer side port.

 Blow-off line pressures were inversely proportional to connector and tubing diameter, and directly proportional to tubing wall thickness. Bentley, Cobe, Gics and Shiley connectors were ranked in accordance with blow-off line pressures generated on Bentley, Harvey and Tygon tubing.

Introduction

The integrity of extracorporeal circuits for cardiopulmonary bypass is dependent on the adequacy of the connectors, tubing and attachment techniques currently available. Clinical grade tubing and disposable connectors are manufactured having a high degree of excellence. However, the conditions in which these devices are used can be suboptimal, resulting in excessive stress beyond the normal operating range. A tubing clamp placed on the arterial line during bypass, aortic cross clamp occluding the perfusion cannula, inadvertent kinking of lines and high flow through small cannula are examples of conditions that can lead to excessive hydrostatic pressure in extracorporeal circuits.

This study was undertaken to compare some of the connectors, tubing, and attachment techniques available, in terms of their relative contributions to maintaining circuit integrity in the face of excessive hydrostatic pressures.

Materials

Connectors made by Bentley, a Cobe, b Gics c and Shiley d were selected as representative of shallow and steep barb designs, (see Figure 1). Each type of connector was tested in 1/4", 3/8" and 1/2" sizes.

Three tubing types, Bentley, Harvey e and Tygon f were selected, based on handling characteristics that indicated possible differences in compliance. Some

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physical properties, obtained from the manufacturers, are listed in Table 1. Each tubing type was tested in \( \frac{1}{4} \), \( \frac{3}{8} \), and \( \frac{1}{2} \) inside diameters. Both \( \frac{1}{16} \) and \( \frac{1}{16} \) wall thickness were used, except in \( \frac{1}{2} \) I.D. where only \( \frac{1}{32} \) wall was tested, due to the lack of resistance to kinking in \( \frac{1}{16} \) wall required for clinical use.

Two attachment techniques for joining tubing and connectors were tested: 'banded,' using Cobe Laboratories locking ties, catalog number 13-112, and tubing 'pushed on' (without additional attachment aides). Tests showed attachments with Bentley locking nuts or Travenol cement (Cat. No. 5M0286), if properly used, can withstand hydrostatic pressures at or above 200 pounds per square inch (PSI), (conversion factor for converting millimeters of mercury to PSI is 0.0193, e.g., \( \text{mmHg} \times 0.0193 = \text{PSI} \)). Due to these high blow-off pressures, they were not tested further. However, locking nuts are relatively more expensive than locking ties (bands), and differences in connector and tubing materials may require individually formulated cements. In addition, when cemented connections are disrupted, pieces of tubing may break away remaining attached to the connector surface, making it difficult to achieve a complete seal, even though a locking tie is placed.

Methods

Three-inch long pieces of tubing were cut, using scissors, and pushed onto the connectors. The connectors and tubing were kept dry and no lubricants were used. In every case the tubing was advanced just beyond the second barb of the connector, in order to standardize the attachments. When bands were used, they were placed between the first and second barb of the connector, in the normal fashion. Bands were secured using a Cobe banding gun (Cat. No. 13-115), set for maximum pull.

\[ \text{TABLE 1} \]

Tubing Physical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Bentley</th>
<th>Harvey</th>
<th>Tygon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Durometer Hardness</td>
<td>70 ± 2</td>
<td>71</td>
<td>64</td>
</tr>
<tr>
<td>Shore A 15 sec.</td>
<td>10 sec.</td>
<td>1600</td>
<td>2000</td>
</tr>
<tr>
<td>Tensile Strength PSI</td>
<td>1900</td>
<td>1600</td>
<td>2000</td>
</tr>
<tr>
<td>Ult. Elongation %</td>
<td>325</td>
<td>375</td>
<td>360</td>
</tr>
<tr>
<td>Tear Resistance lbs./in</td>
<td>150</td>
<td>159</td>
<td>164</td>
</tr>
</tbody>
</table>

\[ \text{FIGURE 1.} \]

\[ \text{FIGURE 2.} \] Hydrostatic test platform used to determine blow-off pressures. The test specimen was connected at the port indicated by “connector attachment.” Water in the “reservoir syringe” was drawn into the “pressure syringe” and injected into the system to apply hydrostatic pressure to the test specimen. Final blow-off pressure, in psi, was indicated by the “pressure gauge” fitted with a peak pressure indicator.
All connectors, with tubing attached, were packaged in peel packs and gas sterilized, to approximate the conditions to which clinical tubing packs would be subjected.

Connector-tubing samples were fitted on the hydrostatic test platform shown in Figure 2. The hydrostatic gauge, manufactured by Ashcroft, was factory calibrated to an accuracy of 0.007% full scale, (0–200 PSI). Samples were connected to the test platform at the point indicated in Figure 2 by “connector attachment.” The system was filled with water from the “reservoir syringe” and a tubing clamp placed on the open end of the tubing of the test sample. A 1 ml or 3 ml syringe was used as a “pressure syringe” to generate hydrostatic pressure. Pressure was increased at an even rate until a sudden drop in pressure indicated failure of the connection by partial or complete blow-off. The pressure gauge is fitted with a peak pressure indicator so that the highest pressure achieved in each test could be determined. All tests were done at room temperature. Each connector-tubing-attachment combination was repeated a minimum of five times. A total number of 600 blow-off determinations were made in the study. Data was analyzed by computer, using an analysis of variance procedure, Duncan’s Multiple Range Test for Variable Pressure.

Results

Connector types, by mean blow-off pressures, are summarized in Figure 3. Cobe was significantly (p < .05) higher than the others, 15.4% higher than Bentley, and Bentley was significantly (p < .05) higher, 19.2%, than Gics and Shiley. Gics and Shiley are not significantly different from each other. A breakdown of all pressure data is available on request.

Tubing types, by mean blow-off pressure, are summarized in Figure 4. They are all significantly (p < .05) different, with Bentley tubing showing the highest

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Ashcroft, Stratford, Conn. 06497
pressure, 12.2% higher than Harvey, and Harvey, 15.9% higher than Tygon.

Attachment techniques, by mean blow-off pressure, are summarized in Figure 5. Tubing attached with bands demonstrated a 19.4% higher blow-off pressure than pushed on.

Connector sizes, by mean blow-off pressure, are summarized in Figure 6. Differences in blow-off pressure due to tubing wall thickness are summarized in Figure 7. These blow-off pressures in Figures 6 & 7 are expected to follow differences in diameter and wall thickness, as predicted by stress analysis in material engineering. Since the pressure data given in these figures are summaries, the difference in connector design and tubing material are incorporated in the data. The increase in blow-off pressure, due to wall thickness, is directly proportional to wall thickness, i.e. if you increase the wall thickness, the blow-off pressure will be increased. An increase in blow-off pressure due to size (diameter), is inversely proportional to diameter. Using a simplified formula to express the latter relationship, we have:

\[ PD = C \]

or

\[ P = \frac{C}{D} \]

The constant, C, entails the wall thickness difference in tubing material and connector design, since the data in Figure 6 are means of different wall thickness, tubing material and connector design for large populations sorted by connector size only. If the data are truly representative, it should be consistent with the relationship \( P = \frac{C}{D} \), where \( PD = C \) and \( C = 17.5 \) for our series.

<table>
<thead>
<tr>
<th>Connector and Tubing Size</th>
<th>Measured Pressure (PSI)</th>
<th>Calculated Pressure (PSI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/4&quot;</td>
<td>69.8</td>
<td>70</td>
</tr>
<tr>
<td>3/8&quot;</td>
<td>47.6</td>
<td>48</td>
</tr>
<tr>
<td>1/2&quot;</td>
<td>35.2</td>
<td>35</td>
</tr>
</tbody>
</table>

The measured vs. calculated pressures are consistent and, therefore, confidence in the data is justified.

The different connector types, by size, are summarized in accordance with the respective mean blow-off pressures, in Figure 8. In the 1/4" size, all types are significantly (p < .05) different. In terms of pressure: Cobe is 16.4% higher than Bentley; Bentley is 21.7% higher than Gics; and Gics is 12.8% higher than Shiley. In the 3/8" size Cobe is significantly (p < .05) higher than the others, Bentley and Shiley are not significantly different from each other, but both are significantly (p < .05) different from Gics. In terms of pressure: Cobe is 15.6% higher than Bentley; Shiley 11% higher than Gics. In the 1/2" size, Cobe and Bentley are not significantly different from each other but are significantly higher than Gics and Shiley. Gics and Shiley are not significantly different from each other. In terms of

FIGURE 6.

FIGURE 7.
pressure, Cobe, the highest, is 31.8% higher than Gics, the lowest.

Discussion

In this study the tubing was advanced on the connectors just beyond the second barb, as a standard. In some of the connector designs, greater blow-off pressure could no doubt be achieved by advancing the tubing further onto the connector. Cobe and Shiley connectors were the least difficult to push the tubing on. Considerable effort was required to push the tubing beyond the second barb with the Gics and Bentley connectors. Factory assembly of tubing packs allows the manufacturer to use specialized equipment and/or appropriate plastic cements to assist in assembly. Those of us who assemble some of our own custom tubing circuits should seek the advice of connector and tubing manufacturers to insure compatibility of material and plastic cements that are so tempting to use for easy assembly. In addition, it has been suggested by some engineers that use of incompatible materials or plastic cements can cause crazing* and/or leaching of plasticizers.**

“Creep”‡ is one of the engineering concepts used to describe the behavior of polymers. Creep is related to the viscoelastic properties of plastics and is affected by temperature and duration of stress. When tubing is pushed on a connector the force exerted by the connector against the wall of the tube causes viscous flow and stress relaxation. The practical result of creep is that even the modest heat of gas sterilization and aeration cause plastic tubing to conform to the shape of the connector, and locking ties seem to loosen as the compressive force is relieved by viscous flow of the tubing. The same phenomena will occur over a longer period of time at room temperature. In a comparison of freshly assembled, unsterilized connector/tubing samples to gas sterilized samples, the latter had a lower blow-off pressure. The idea that it is safe to use modern connectors for the arterial cannula without the use of locking ties is quite correct. This is partly due to the lack of the effect of creep on the freshly assembled connection. Cannula connections on long-term membrane support circuits may find the effect of creep requires some locking devices for safety, if they are not already universally used.

Normal arterial line pressures experienced with proper cannula selection for required flow rates can keep line pressure below 10 PSI. Abnormal conditions causing excessive line pressure can exceed the blow-off pressure of most connector/tubing circuit designs. The connectors in this study show some differences in design with resulting differences in line pressure. However, they were all satisfactory for normal operating conditions.

The tubing wall thickness for each tubing type was measured and found to be the same from one type to another for each wall thickness.

It is not obvious why there were the observed differences in blow-off pressure for connector and tubing types. Evidently the small differences in maximum diameter for connectors, and tubing formulation differences for tubing, were responsible. Additional information on the physical characteristics of the products tested here, in the product literature, would be helpful if high stress circuits need to be designed. Creep modulus*** and Young’s modulus† for tubing and factory tested blow-off pressures are examples of information we would consider desirable.

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* A craze is a region of material permanently deformed. The deformation can reduce material density 50%. The crazing seen in connectors has the appearance of spider web-like fractures at the surface.

** Plasticizers are low molecular weight polymers used in thermoplastics to make them more pliable.

*** Creep modulus is the force per unit area to produce a plastic, i.e. permanent, strain per unit length in a given time at a given temperature.

† Young’s modulus is the force per unit area to produce an elastic, i.e. reversible, strain per unit length at a given temperature.
Conclusions

Current connector designs are more than adequate for normal cardiopulmonary bypass line pressures and will maintain circuit integrity. Only suboptimal conditions due to obstruction of normal flow will result in failure.

It is recommended that some form of tie or locking nut be used for tubing connections, due to the effects of creep that occur with exposure to moderate temperature and extended storage time.

If plastic cements are used for assembly of tubing circuits, the manufacturer of each product used should be consulted.

Acknowledgments

We would like to thank Shiley Laboratories for their assistance and advice in preparing to do this study. The blow-off technique used in our study was suggested by their engineering staff. Special thanks to Daniel R. Johnston, manager of the engineering Laboratory at Shiley Scientific.

References

2. Ibid, p—317