Flow Rate Stability of Medical Peristaltic Pump Tubing Materials

Dominik Szyk
Research Engineer
Saint-Gobain Research North America
9 Goddard Road,
Northboro, MA, 01532

Kristina Dempsey
Marketing Manager – Saint-Gobain Medical Components
2316 W Wisconsin St,
Portage, WI 53901

Charles Golub
Market Development Manager – Saint-Gobain Medical Components
Saint-Gobain Research North America
9 Goddard Road, 01532

Introduction:
Positive displacement pumps, more specifically peristaltic pumps, are a critical component to many medical procedures. Two such procedures are the intravenous infusion of fluids and enteral feeding. In both of these procedures, the stability of flow is critical for the patient’s care. Specialty tubing formulations across a number of material solutions can be used for such critical, life saving devices. In order to understand how each material family and specialty product performs, an investigation was conducted into the two aforementioned medical applications where flow rate is critical. Each pump for peristaltic pumping has its own unique design and as such, performances vary from product to product. Factors such as occlusion percentage, method to achieve occlusion (rollers, fingers, paddles), type of drive used (DC vs AC) and other such pump design factors are all critical to the end performance and will play a role in tube selection to meet the final product needs.

Materials and Methods:
This study examined the performance of 7 samples on two different types of pumps. The materials used can be segmented into three main types; thermoplastic elastomers (TPEs), polyvinylchloride (PVCs), and silicones. Each material type has trade-offs, such as ability to bond to other materials. Thus, three material families were chosen to provide options for a pump manufacturer. Materials such as SaniPure™ BDF™, PharMed® BPT, and Tygon S3™ E-LFL are known in the biopharmaceutical processing market as excellent pump tubes and thus were selected to be part of this investigation into medical pump applications. The pumps chosen are each considered to be the market leaders for their respective intended applications, enteral feeding and infusion. The chart below indicates which tubes were tested as well as in which pumps they were tested.
Table 1. Tubing samples used in this study, along with the pump used for testing

<table>
<thead>
<tr>
<th>Material Class</th>
<th>Sample</th>
<th>Tested on Infusion Pump</th>
<th>Tested on Enteral Feeding Pump</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPE</td>
<td>SaniPure™ BDF™</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>PharMed® BPT</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PVC</td>
<td>Tygon S3™ E-LFL</td>
<td>X</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Tygon® S-97-E</td>
<td>X</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Tygon® ND-100-55</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Silicone</td>
<td>Bio-Sil® Precision</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Bio-Sil® 1565</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Figure 1. Enteral feeding pump used for testing (left). Infusion pump used for testing (right)

Pump Protocol

The testing consists of two parts; the break-in and the sampling. The tubes are placed in the pump, primed (meaning the fluid fills the tube so pumping can begin), and then the tubes are broken-in. This can sometimes be referred to as conditioning the tubes. The ideology behind this step is that elastomers will take a set over time when placed in high strain environments such as a peristaltic pump. This, in turn, will reduce the flow rate. By exposing the tubes to high strain when initially placed in the pump, it will artificially break the tubes in. With that, they will take less of a set over the remainder of the pump timing providing a more stable flow rate over time. Since each pump is different, a different break-in condition was used for each. Manufacturers’ recommendations were considered when designing the break-in conditions. Water was used as the pumped fluid.
**Conditioning or Break-in Procedure:**

**Enteral Feeding Pump:**

The tube sample was cut to 4.75” lengths. The tubes were placed in the pump and primed, then conditioned for a minimum of 45 seconds prior to the initial reading.

**Infusion Pump:**

Samples were cut to 5.75” lengths. The tubes were placed in the pump and primed, then conditioned for a minimum of 35 seconds prior to the initial reading.

**Pump Procedure:**

**Enteral Feeding Pump:**

The feeding pump was operated at a continuous flow rate of 100 mL/min over a duration of 24 hours. A flow rate reading occurred at the following five time intervals: instantaneous, one hour, two hours, four hours, and 24 hours. Samples were collected at each time interval and weighed over a 30-minute time period.

**Infusion Pump:**

The pump was operated continuously at 125 mL/min, also for 24 hours. A flow rate reading occurred at the following five time intervals: instantaneous, one hour, two hours, four hours, and 24 hours. Samples were collected at each time interval and weighed over a 10-minute time period.
Results:

*SaniPure™ BDF™:

The SaniPure™ BDF™ tube experienced a flow rate change of 7% over the 24 hour pumping duration for the enteral feeding pump with most of that loss occurring over the first 2 hours. This initial drop in flow rate could possibly be rectified by using a more extensive break in procedure such as longer time conditioning or higher RPMs, or both, although only a 5% drop in flow rate is often considered negligible. The flow rate is very stable after the initial drop that occurred within 2 hours of operation.

When tested in the infusion pump, the flow rate had a very minimal change of only 2%. For this pump, the tube was very consistent over the time tested.

![Graph of SaniPure™ BDF™: Enteral Feeding Pump](image1)

*error bars represent standard error (SE)

*Figure 2. Flow Rate Change of SaniPure™ BDF™ for Each Pump*
PharMed® BPT:

PharMed® BPT tubing experienced a flow rate change of 7% with the enteral feeding pump and a rate change of 3% for the infusion pump after 24 hours. The flow rate change was consistent and steady throughout each of the time intervals with the enteral feeding pump.

In the infusion pump test, most of the change in flow occurred within the first 4 hours of pumping. There was minimal change noted during the remainder of the testing period.

*error bars represent standard error (SE)

**Figure 3.** Flow Rate Change of *PharMed® BPT* for Each Pump
**Bio-Sil® Precision**

The Bio-Sil® Precision tube performed well on each of the pump modules. The flow rate change was observed to be just under 4% for the enteral feeding pump. There is more of a change observed in the first 4 hours of operation before the rate of change becomes more consistent up to the completion of the 24 hours of pumping.

The observed flow rate change on the infusion pump was 2% over the 24 hours. The change was observed to be stable and consistent over the duration of the testing.

*error bars represent standard error (SE)*

**Figure 4.** Flow Rate Change of Bio-Sil® Precision tubing for Each Pump
**Tygon® ND-100-55**

The Tygon® ND-100-55 tube was observed to have a flow rate change of 1% after 24 hours of pumping in the enteral feeding pump. The flow rate change initially takes a dip after the first hour before regaining the initial flow after 4 hours. During this time, the tube is still being conditioned and worked onto the pump rotor.

After 24 hours of pumping with the infusion pump, the flow rate change was just over 2%. While this is a minimal amount of variation, the majority of this change occurs within the first 2 hours of pumping, before stabilizing for the reminder of the testing duration.

*Figure 5. Flow Rate Change of Tygon® ND-100-55 for Each Pump*
Bio-Sil® 1565

In enteral feeding pumps, the Bio-Sil® 1565 tube experienced a flow loss of 6% after the 24 hour testing cycle. The flow change was observed to be stable from the instantaneous reading until the final measurement at 24 hours.

The majority of flow change for the infusion pump was observed in the first 2 hours of pumping. After this time period, the flow change is able to stabilize until the end of the duration of operation. The tube is still being worked in at the initial 2 hours from the start of pumping.

*error bars represent standard error (SE)

Figure 6. Flow Rate Change of Bio-Sil® 1565 for Each Pump
**Tygon® S-97-E**

Tygon® S-97-E was only tested on the Infusion pump. This tubing experienced a flow rate change of 1% after the 24 hour testing cycle. There appeared to be a slight increase in flow in the first few hours of pumping. A more extensive break-in period to better condition the tube would provide a more stable initial flow, as this initial flow rate increase is sometimes noted in materials where the material softens within the first hour of pumping making the orifice slightly larger. If the softening could take place during “break-in”, often a more stable flow rate is realized.

![Graph showing flow rate change for Tygon® S-97-E](image)

*error bars represent standard error (SE)*

**Figure 7. Flow Rate Change of Tygon® S-97-E for Infusion Pump**

**Tygon® S3™ E-LFL**

The Tygon® S3™ E-LFL tube demonstrated superior flow rate stability when tested in the infusion pump. After the completion of the 24 hour testing cycle, the change in flow rate was 1%. It was stable and consistent over the testing period having no sharp increases or decreases.

![Graph showing flow rate change for Tygon® S3™ E-LFL](image)

*error bars represent standard error (SE)*

**Figure 8. Flow Rate Change of Tygon® S3™ E-LFL for Infusion Pump**
Conclusion

Saint-Gobain’s broad portfolio of pump tubing products offer a tube for every potential need. In this case medical pumping applications were specifically studied. Flow rate consistency is critical to two medical pump applications: enteral feeding and infusion. Three main families of tube materials (Silicones, PVCs, and TPEs) were selected for this flow rate consistency study on two types of pumps. Each tube was pumped continuously for 24 hours, without interruption, as laid out in the pump protocol section in this report.

**Enteral Feeding**

**Table 2. Summary of flow change results for tubes tested on the enteral feeding pump**

<table>
<thead>
<tr>
<th>Material ID</th>
<th>Maximum flow rate % change after 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>SaniPure™ BDF™</td>
<td>6 %</td>
</tr>
<tr>
<td>PharMed® BPT</td>
<td>7 %</td>
</tr>
<tr>
<td>Bio-Sil® Precision</td>
<td>4 %</td>
</tr>
<tr>
<td>Tygon® ND-100-55</td>
<td>2 %</td>
</tr>
<tr>
<td>Bio-Sil® 1565</td>
<td>6 %</td>
</tr>
</tbody>
</table>

It was noted during this study that many enteral feeding pumps, and possibly other peristaltic pumps, require the tube to be stretched before loading in the pump. In those applications, PVCs may not be the best option. PVCs offer great clarity, are easy to bond to and can have custom formulations for a number of applications. However, most do not have the high elongation property that silicones or other TPEs offer. For this reason, a silicone or TPE such as SaniPure™ BDF™ would be a good option for enteral feeding, flow rate changes were observed to be 7 % or less during the duration of pumping

**Infusion Pump**

**Table 3. Summary of flow change results for tubes tested on the infusion pump**

<table>
<thead>
<tr>
<th>Material ID</th>
<th>Maximum flow rate % change after 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>SaniPure™ BDF™</td>
<td>2 %</td>
</tr>
<tr>
<td>PharMed® BPT</td>
<td>3 %</td>
</tr>
<tr>
<td>Bio-Sil® Precision</td>
<td>2 %</td>
</tr>
<tr>
<td>Tygon® ND-100-55</td>
<td>2 %</td>
</tr>
<tr>
<td>Bio-Sil® 1565</td>
<td>3 %</td>
</tr>
<tr>
<td>Tygon® S-97-E</td>
<td>2 %</td>
</tr>
<tr>
<td>Tygon® S3™ E-LFL</td>
<td>2 %</td>
</tr>
</tbody>
</table>
A number of tubes did well in the continuous flow rate pump analysis in the infusion pump, but with varying degrees of initial performance. With that, the conditioning period for the application and tube should be understood when selecting the right tube for infusion applications. The silicone and PVC formulations that were tested both performed exceptionally well and in many pumps would be excellent choices for this application. Maximum flow rate changes were observed to be 3% or less for the tubes used in this study.

Flow rate stability for continuous pump operation is just one factor to consider when selecting a proper tube for medical pump applications. Many other performance factors should be considered in order to ensure optimal pump performance. In addition to the broad portfolio of products which demonstrated good continuous flow stability performance, Saint-Gobain offers a number of additional custom formulations or the ability to custom blend a formulation to meet specific pump performance requirements. An added benefit that ensures our product will continue to meet demands of medical pump applications is the superior tolerance and processing capabilities Saint-Gobain can offer. Finally, working closely with your tubing provider can help to design a system where the break in procedure perfectly aligns with the needs of the pumping application.

For further inquiries, please email us at medical@saint-gobain.com