**Infusion Pump Design For SCIg: Theoretical Considerations**

**PRESSURE VS. TIME**

- **Constant Pressure vs Constant Flow**
- **Constant Flow Pumps** will increase pressure (yellow line), if necessary to maintain a set flow rate.
- **Constant Pressure Pumps** will slow down the flow of the drug (blue line), corresponding to increases in resistance at the patient’s infusion site.

**DYNAMIC EQUILIBRIUM (Constant Pressure) vs. CONSTANT FLOW**

- **Constant Pressure Source** - Maintains a certain pressure. Flow rate is controlled by the resistance to flow of the tubing and needle sets, the viscosity of the drug, and the ability of the patient’s infusion site to accept drugs.
- **Constant Flow Source** - Maintains a certain flow rate. Pressure varies based on the resistance of tubing and needle sets, drug viscosity, site acceptance, and occlusion (overpressure) alarm setting.

**SIGNIFICANT SITE REACTIONS**

- Images of site reactions following SCIg infusion: automatic pumps increases the risk of site reactions.
- Flow rate is key when infusing into limited subcutaneous spaces.

**Introduction:** Subcutaneous administration of Immunoglobulin G (SCIg) places new demands on infusion pumps. Most portable pumps are not designed for high loads and back pressures. Electronic pumps continue to be based on volumetric delivery, making them Constant Flow Sources (CFS). Constant Flow delivery tends to produce uncontrollable high pressures when delivering into volume restricted areas, such as subcutaneous spaces, which can result in site complications and pain. An alternative method, the Constant Pressure Source (CPS) is widely used to infuse IgG. This device is design limited to 13.5PSI. Directly comparing the performance of CPS and CFS delivery devices is possible by constraining each system’s different response to increasing pressure.

**Objective:** To create a theoretical model to explain how infusion pumps work, and what benefits and liabilities the CPS and CFS would have for subcutaneous administrations.

**Aim:** To find factors which minimize SCIg patient discomfort.

**Methods:** We created a theoretical model of IgG infusion. We ran the model with the CPS and CFS, then compared with laboratory and clinical results to test the model’s accuracy.

**Results:** The CPS (Constant Pressure Source) model predicts flow that decreases proportionally to back pressure (saturation) at the site. This automatic balance is referred to as Dynamic Equilibrium. CFS pumps infuse until and unless a high pressure limit is reached, then cease to operate. The CPS tends to produce high pressures (20-70PSI) when delivering into the subcutaneous matrix, which can result in tissue damage, site complications, and pain. World literature encourages pressures ≤15PSI.

**Conclusions:** The model correlates with clinical results. Viscous drugs at faster flow rates led to premature failures among several models of CFS (Electronic pumps) under strain from increased back pressure. Higher delivery pressures from the CPS also worsened patient discomfort. Patients using the CPS (FREEDOM60™) noted better delivery with less severe, lower frequency site complications. Patients experienced greater pump reliability, and are more comfortable setting these pumps at a higher rate, knowing the pump automatically slows the infusion in the case of tissue saturation. Overall, this results in faster delivery and less discomfort.

Although not specifically studied in this evaluation, patient feedback indicated short needles sometimes exacerbate site reactions, and that a fast infusion into a limited number of sites increases the prevalence of site complications. Through careful needle set selection, slower infusion, or by increasing the number of sites, SCIg with minimal or no local reactions may be possible. Determining the relative effects of these parameters is a goal for future studies.