Infusion Pump Design For SCIg: Theoretical Considerations

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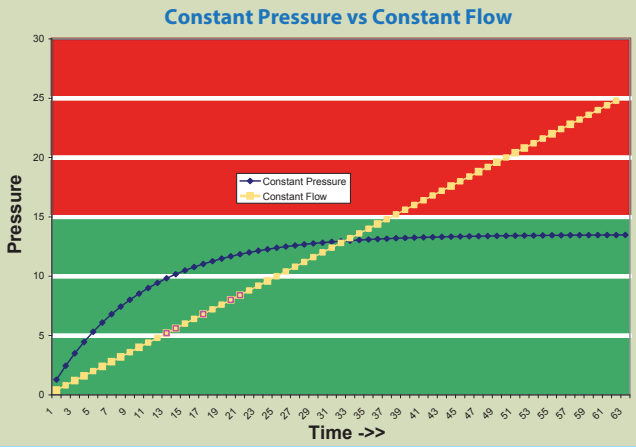
PRESSURE VS. TIME

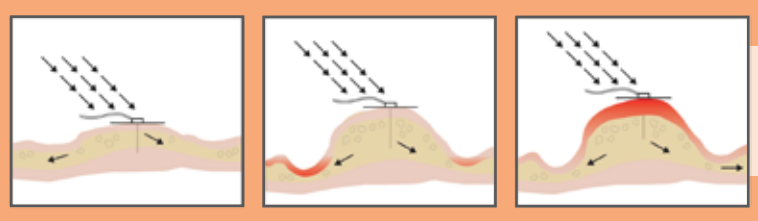


Constant Flow Pumps will increase pressure (yellow line), if necessary to maintain a set flow rate. Constant Pressure Pumps will slow down the flow of the drugs (blue line), corresponding to increases in resistance as patient's infusion sites fill.

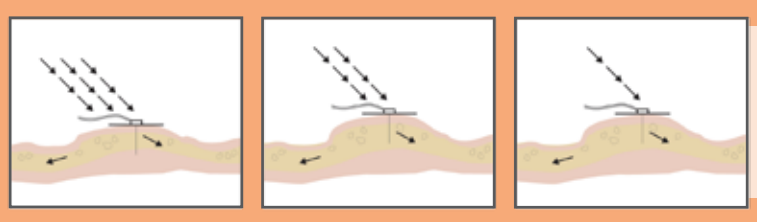
Constant Pressure Source - Maintains a certain pressure. Flow rate is controlled by the resistance to flow of the tubing and needle sets, the viscosity of the drug, and the ability of the patient's infusion site to accept drugs.

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.

DYNAMIC EQUILIBRIUM (Constant Pressure) vs. CONSTANT FLOW

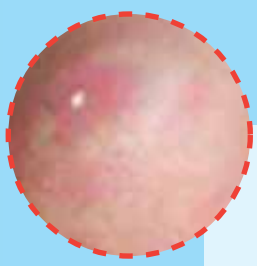


Constant Flow Pumps, or Electric Pumps, are capable of high pressures and do not respond to tissue saturation at infusion sites.



Constant Pressure Pumps operate in Dynamic Equilibrium. They immediately and automatically decrease flow rate in proportion to the patient's site pressures, maintaining a safe limited pressure as sites fill and tissues saturate, resulting in less discomfort.

SIGNIFICANT SITE REACTIONS



Images of site reactions following SCIg infusion:
The flow profile of electronic pumps increases the risk of site reactions.

Flow rate is key when infusing into limited subcutaneous spaces.

The dynamic change in flow rate of the Constant Pressure Source (FREEDOM60™) allows a tapering-down toward the rate of tissue perfusion, without causing increases in pressure. The flow profile of the Constant Pressure Pump reduced the potential for tissue damage and site reactions, such as those shown above.

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 CFS and CPS delivery devices is only possible by considering 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 CFS and CPS, 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 CFS 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 CFS 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.

Support Studies:
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Disclosure:
Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
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Paul Mark Baker, M.D.: Member, Board of Directors, Repro-Med Systems, Inc.
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