A Novel Approach to Customizing the Flow Profile for the Administration of Subcutaneous Immunoglobulins Using 'Dynamic Equilibrium' to Minimize or Eliminate Site Reactions – a Case Report

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INTRODUCTION AND BACKGROUND

Every Subcutaneous Immunoglobulin (SCIg) patient deserves a pain free infusion each time an administration is performed. This has been difficult to ensure until the development of a novel infusion system that facilitates monitoring and modifying the flow rate during the actual Infusion. Site reactions have been considered "common and expected." The Insignis™ Syringe Infusion System determines the patency of the sites and enables real-time flow rate adjustment, which may help minimize site reactions caused by pressure, or stop them before they begin. The objective of this case study was to confirm the theoretical prediction that such a system could perform in the clinical environment, creating a breakthrough for SCIg patients.

METHOD

An experienced SCIg patient was selected to deliver 50ml of immune globulin (Ig) using a three-leg (three 26G needles) OneSett™ Subcutaneous Administration Set. The infusion began at the maximum allowed flow rate, per the product insert, and was monitored during the infusion. If any decrease in rate was noted, the flow rate setting was manually reduced. An assessment of the sites was completed immediately after the infusion.

After setting the controller, the patient noted the volume in the syringe, and a stopwatch was started. The remaining volume was noted after 10 and 20 minutes. Actual flow rates calculated were: 67ml/hr after 10ml and 50ml/hr after 20ml, showing a decrease in the infusion speed. Since the system is sensitive to differential pressure (termed "Dynamic Equilibrium"), a detectable decrease indicates that the initial flow rate was creating tension from the added fluid in the subcutaneous space. After infusing 35ml, the flow rate was manually decreased to 25ml/hr and continued at this rate until the end of the infusion with no further impairment or evidence of tissue saturation.

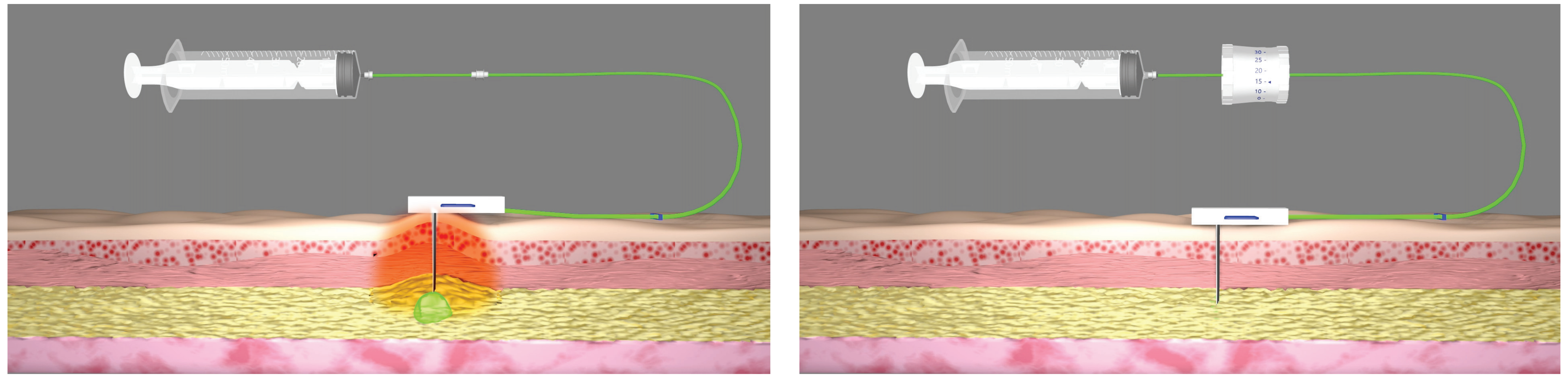

Figure 1. Simulated subcutaneous infusion showing early signs of a site reaction (adverse event) during an infusion without use of the OneSett as compared to an infusion using the OneSett.

References:
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Ochs HD, Gupta S, Kiessling P, Nicolay U, Berger M, Group SIS. Safety and Efficacy of Self-Administered Subcutaneous Immunoglobulin in Patients With Primary Immunodeficiency Diseases. J Clin Immunol (2006) 26(3):265–73. doi: 10.1007/s10875-006-9021-7.
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Figure 2. Onesett™ Subcutaneous Administration Set - 3 leg.

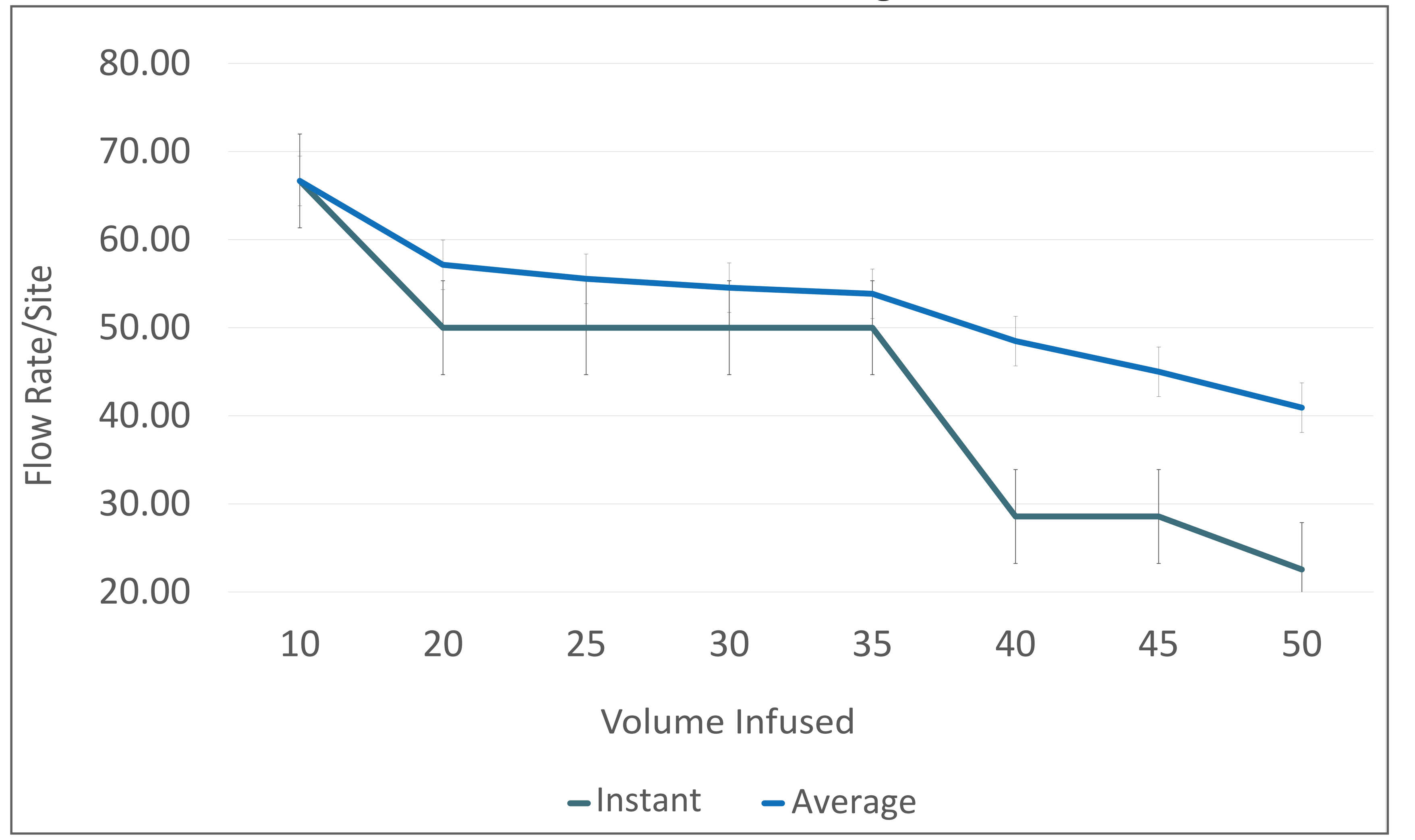

Figure 3. Instant & Average Flow Rate graph shows the flow rate response to dynamic equilibrium and infusion customization using selectable rate flow control (OneSett™). Dynamic equilibrium works to sense site irritation; selectable rate flow control (OneSett™) enables the patient to decrease the flow rate in real-time to help eliminate site reaction occurrence.

RESULTS

Total time of infusion for 50ml was 24:26 minutes. The patient commented that he could "feel" improvement in the reduced flow rate. At the end of the infusion when the needles were removed, there was no redness, pain, leaking, or any site sequalae.

DISCUSSION

Theory has long predicted that subcutaneous immunoglobulin administrations can begin at the highest flow rate- but may need to be decreased during the procedure to prevent site reactions. This is due to the fact that at the beginning of the infusion, the sites, or depots, are empty. Under high flow rates, sites may quickly fill with drug, decreasing tissue perfusion. To deliver the fastest flow rates possible in the shortest amount of time, the objective is to begin the infusion at the highest rate and then manually decrease it as the sites begin to fill or saturate. This new approach has the capability to revolutionize SCIg administrations, providing infusions in minimal time with little or no adverse site reactions.

CONCLUSION

The application of 'dynamic equilibrium' has the potential to revolutionize subcutaneous infusions and improve patient outcomes for those who infuse immunoglobulins subcutaneously.

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