A Novel Approach to Customizing the Flow Profile for the Administration of Subcutaneous Immunoglobulins for Individual Infusions with Benefits to Minimize or Eliminate Site Reactions– A CASE STUDY

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OBJECTIVE

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.

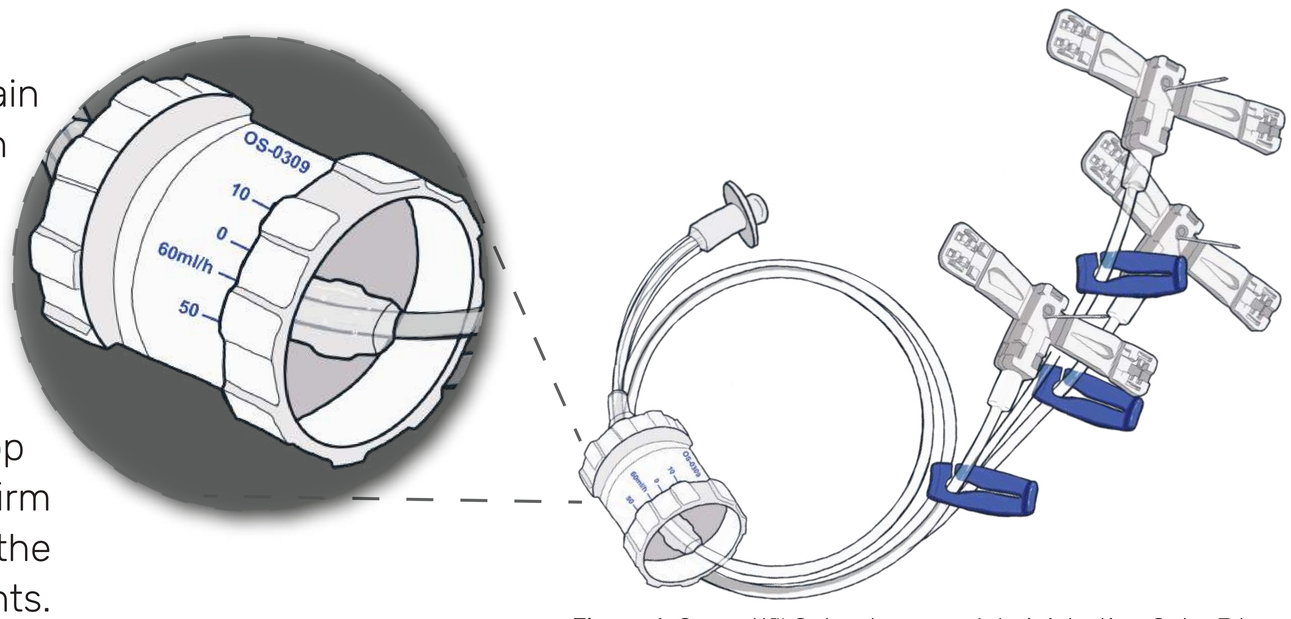


Figure 1. Onesett™ Subcutaneous Administration Set - 3 leg.

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 highest flow rate and was monitored during the procedure. After setting controller, the patient noted the volume in the syringe, and a stopwatch was started. The remaining volume was noted after 10 and 20 minutes consecutively. Actual flow rates calculated: 67ml/hr after 10ml and 50ml/hr after 20ml. After infusing 35ml, the flow rate was manually decreased to 25ml/hr and continued to the end without further impairment of flow rate or evidence of tissue saturation.

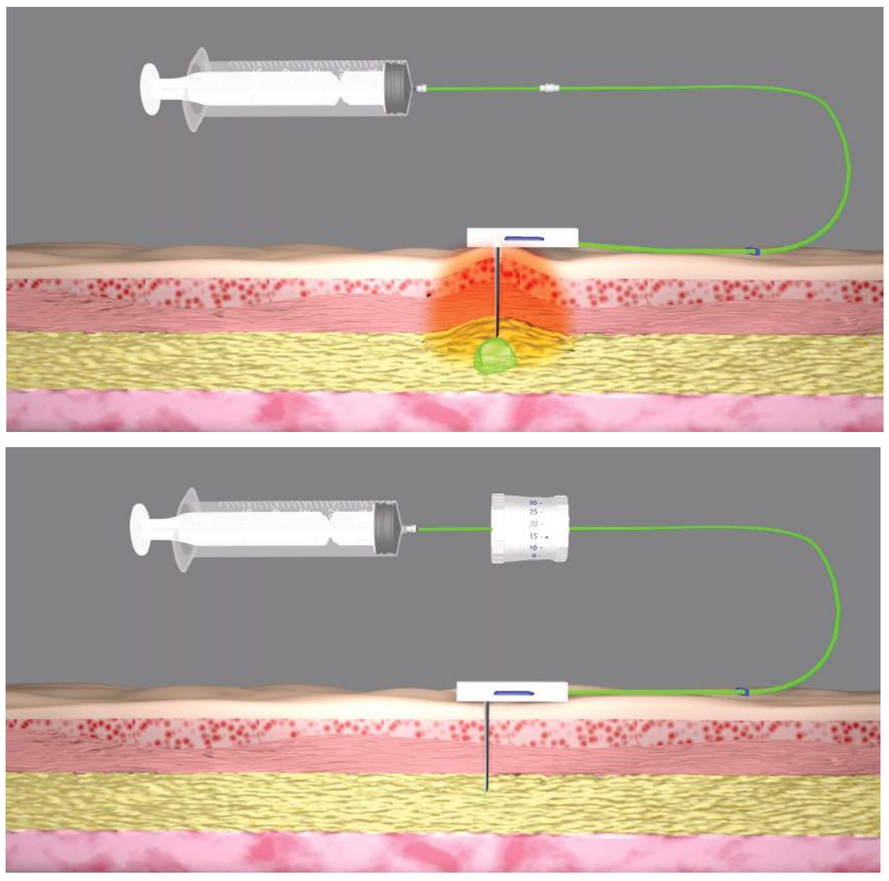
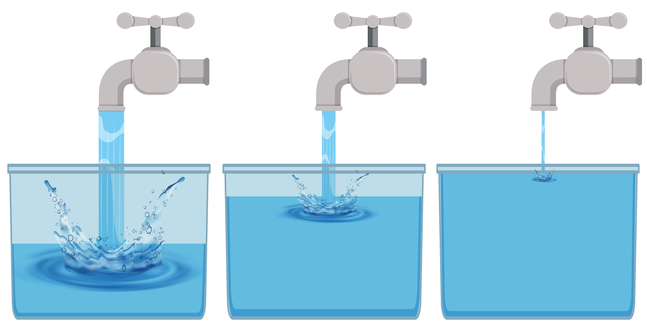


Figure 2. Simulated subcutaneous infusion showing early signs of a site reaction (adverse event) during an infusion without use of the OneSett as compared to an infusion using the OneSett.

An anology:

Think of the water buckets as subcutaneous "depots" under the skin where medication is infused. As the infusion progresses, the depots become increasingly saturated. The ability to taper the flow rate is analogous to the ability to easily adjust the rate of the water filling the buckets with the turn of the dial.



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 other site sequalae.

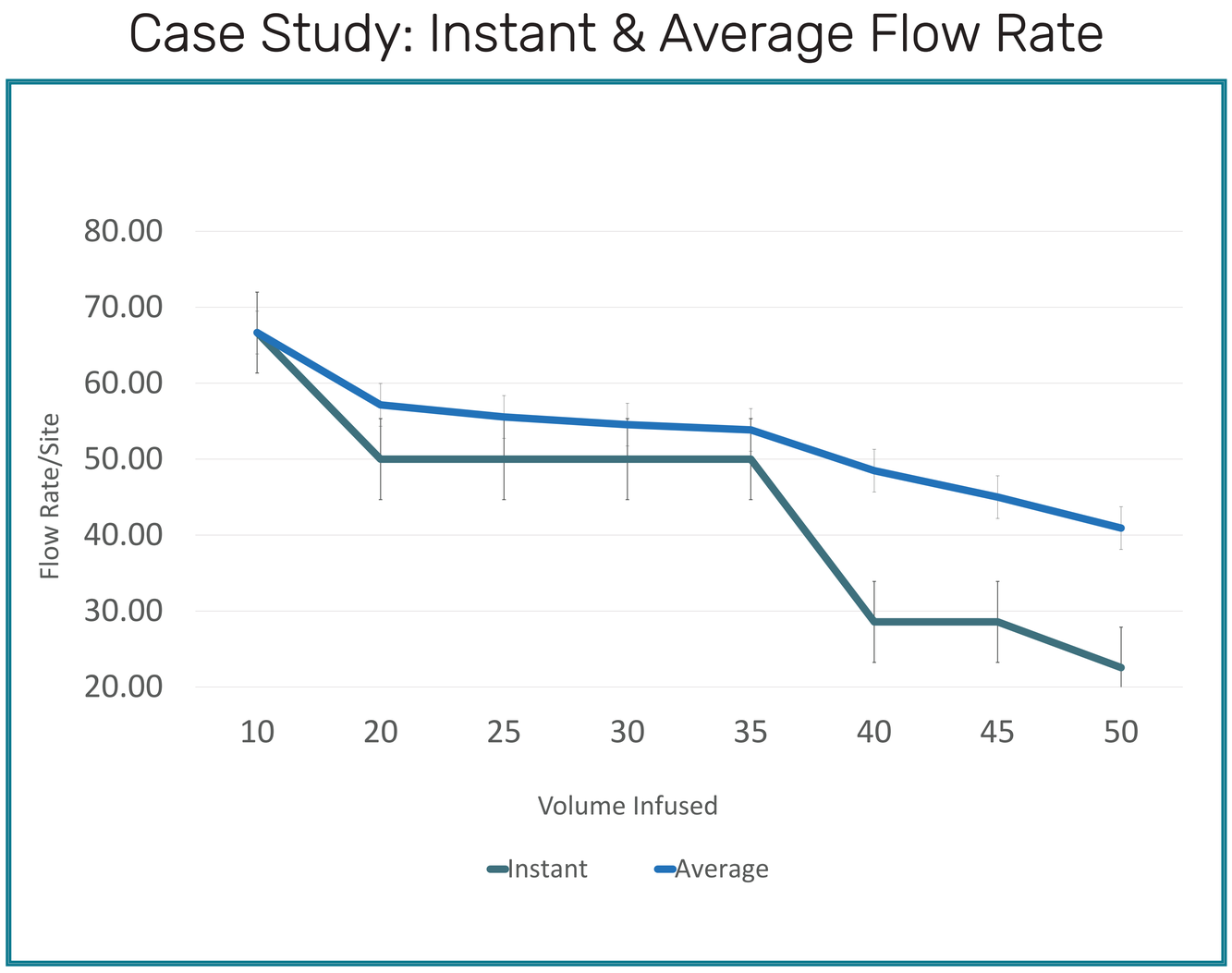


Figure 3: Instant & Average Flow Rate shows the flow rate response to dynamic equilibrium and customization using selectable rate flow control (OneSett™). Dynamic equilibrium works to sense site irritation; selectable rate flow control (OneSett™) enables the patient to decrease the flow rate in real-time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

CONCLUSION

To deliver the fastest flow rates possible in the least amount of time, it is possible to begin the infusion at the highest flow rate (per drug package insert) and manually decrease as the sites begin to fill. This new approach has the capability to revolutionize SCIg administrations, providing infusions in minimal time with little or no adverse site reactions.

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