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– CASE STUDY

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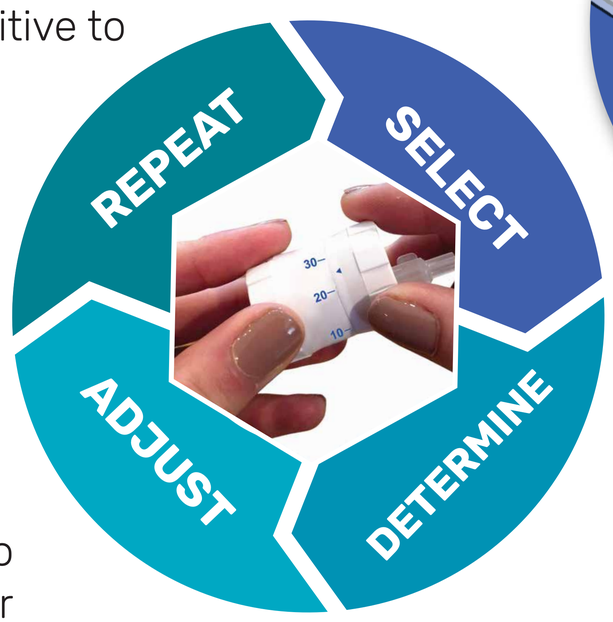
OBJECTIVE

Ideally, every Subcutaneous Immunoglobulin (SCIg) patient deserves a pain free infusion every time an administration is performed. This has been difficult to ensure until the development of a novel infusion system to facilitate monitoring and modifying the flow rate during the actual Infusion. This system can determine the patency of the sites for each infusion and enables real-time flow rate adjustment. The reactions patient have complained of can be minimized or stopped before they start. 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 patients who infuse subcutaneous immunoglobulin.

METHOD

After setting the OneSett™, 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 were calculated to be 67ml/hr after 10m and 50ml/hr after 20ml, showing a decreased speed. Since the system is sensitive to differential pressure (termed "Dynamic Equilibrium"), a detectable decrease indicated 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 to the end with no further impairment of flow rate or evidence of tissue saturation.



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.

CONCLUSION

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 caused by beginning with empty depots in the subcutaneous space which under high flow rates may quickly fill with drug- decreasing tissue perfusion. To deliver the fastest flow rates possible and therefore the minimum time of infusion, 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.

DESIGN

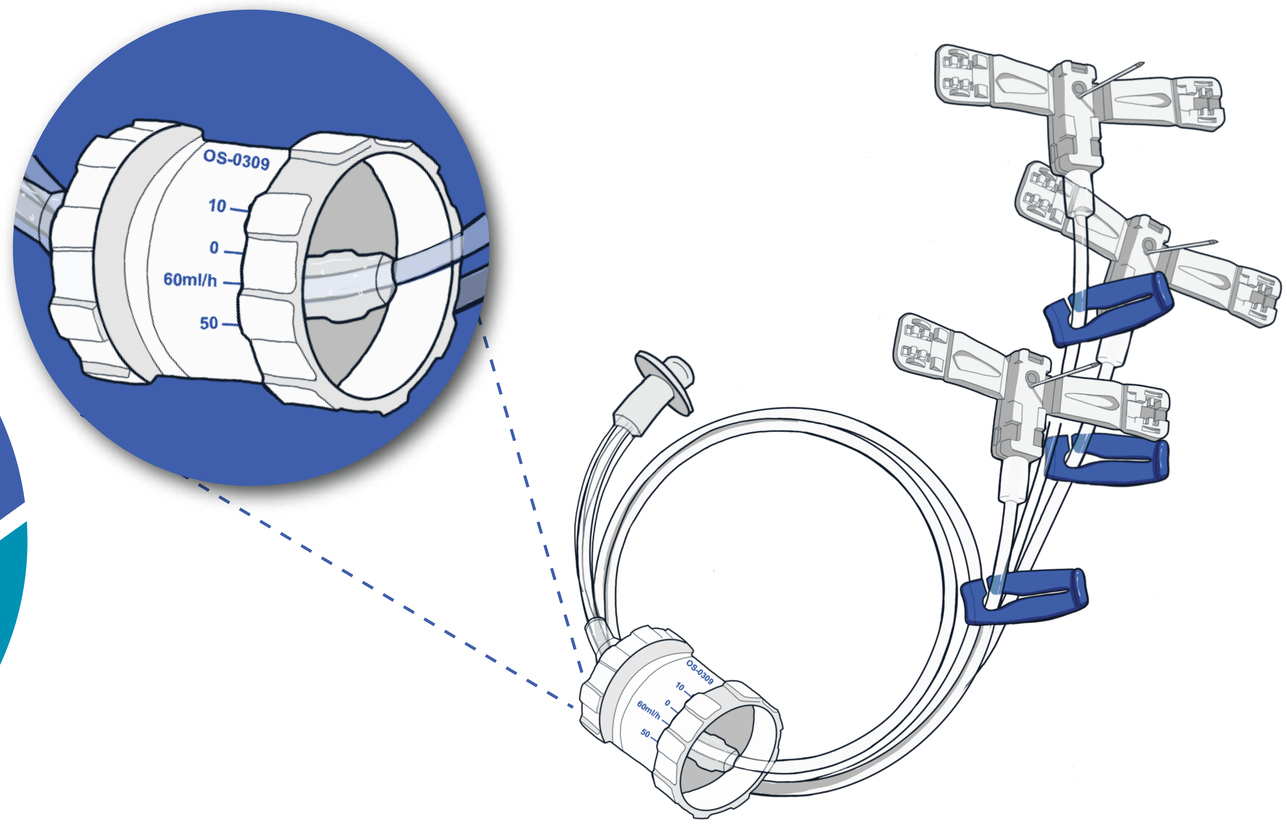
An experienced SCIg patient was selected to deliver 50ml using the OneSett™ (three 26G needles) and a 13.5psi mechanical syringe infusion driver. The infusion began at the highest flow rate and was monitored during the procedure. If any decrease in rate was noted, the setting was manually reduced. An assessment of the sites was completed immediately after the infusion.

OneSett™ Subcutaneous Administration Set -

*3 site configuration**

The OneSett™ is a selectable rate flow controller and 26G subcutaneous needle set connected in one piece, calibrated to deliver 10-60ml/hr/site.

**Flow rate on the dial is the flow rate delivered to each needle site.*



Case Study: Instant & Average Flow Rate

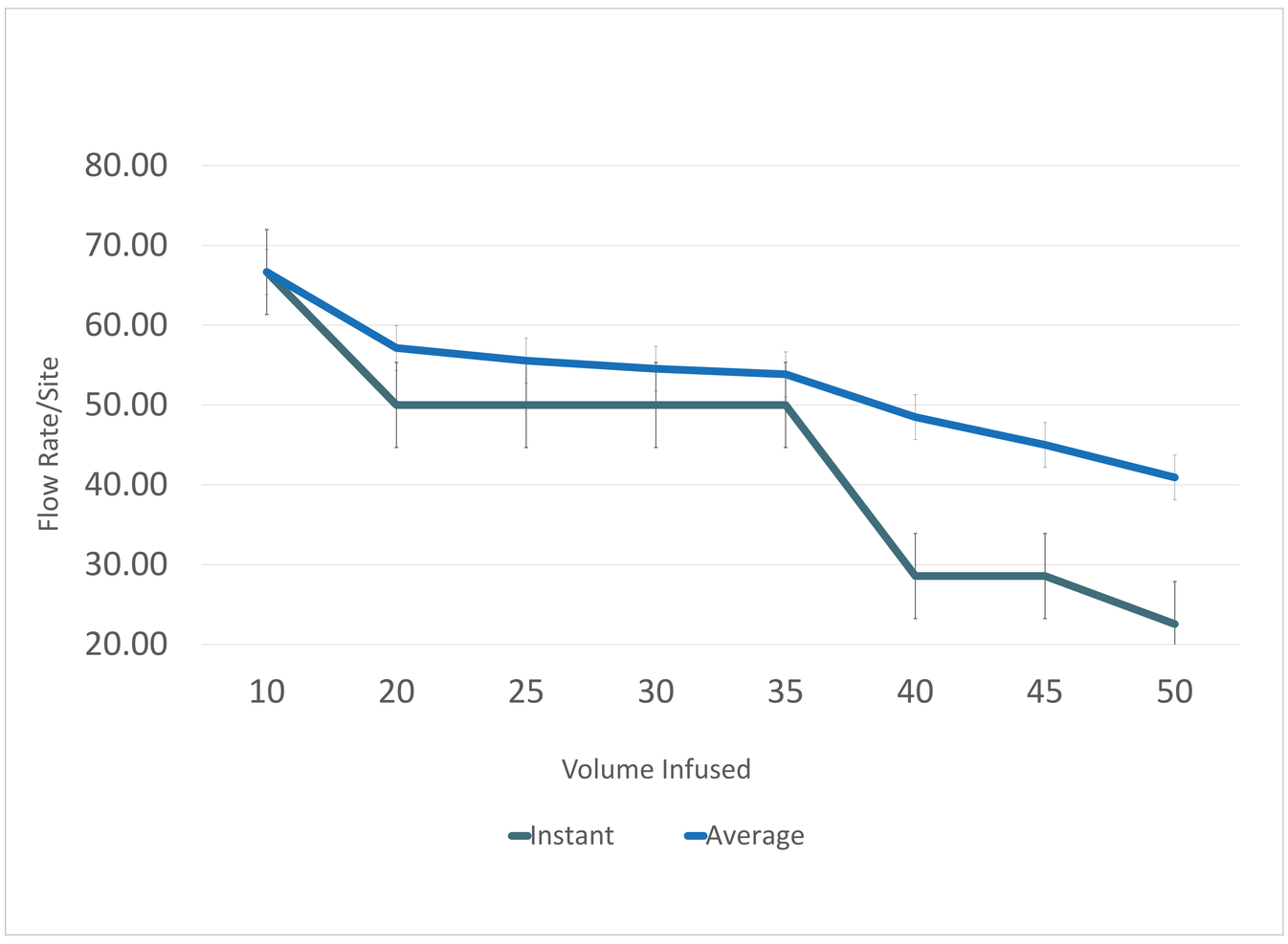


Figure 1: Instant & Average Flow Rate shows the flow rate response to dynamic equilibrium and customization using selectable rate flow control (OneSett™). Dynamic equilibrium works to sense site irritation; selectable rate flow control (OneSett™) enables the patient to decrease the flow rate in real-time to help eliminate site reaction occurrence.

ANALOGY:

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.

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