Impact of Needle Sets on Patient Infusion Site Reactions from Delivery of Subcutaneous IgG (SCIg)

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Introduction: Optimal SCIg infusion may depend on needle size, tip performance, flow consistency, and type of cover dressing. Poor needle design and quality could exacerbate complications of site pressurization, which forces IgG into dermal layers containing mast cells, and may contribute to local site reactions.

Objective: To determine if adverse injection site outcomes can be mitigated through changes in needle-set performance.

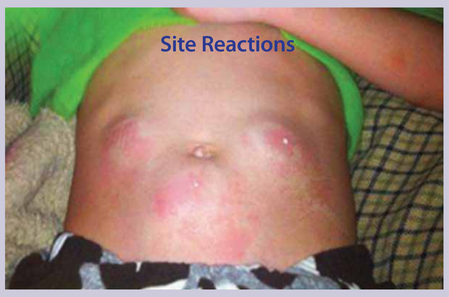
Aim: To find factors which minimize SCIg patient discomfort.

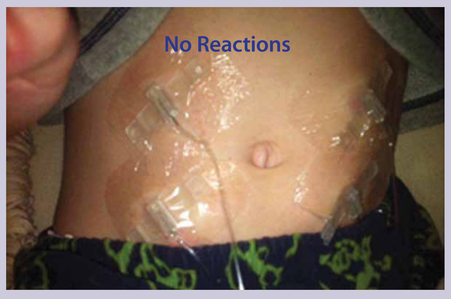
Methods: Baseline correlation was achieved for all subcutaneous needle sets on the market, by comparing needle force data with optical measurement, including assessment of damage at the tip of the needle. We then tested needle tip sensitivity on 30 volunteers, and provided RMS HIgH-Flo™ needle sets to fourteen other patients who had reported adverse site reactions with their previous needle sets (from several manufacturers). Patient experience was evaluated regarding pain on needle insertion, site reactions, and ease of needle insertion/set use compared with their previous needle set.

Results: 29 out of 30 of patients reported less pain on insertion with the new needle set. In a separate cohort of 14 patients who expressed specific site complaints following their SCIG infusions, all 14 reported significantly fewer local adverse reactions (induration, redness, discomfort) after switching to the new needle sets. They also reported improvement in solution flow and administration time when no other parameters (infusion pump, volume or concentration of drug) were changed. The new needle sets were identified in the lab as having the best overall performance, including more "even" flow characteristics to each needle in the multi-needle set, least amount of out-of-the-box damage at the needle-tip, and optimized bevel for subcutaneous administration.

Conclusions: Patients are capable of sensing needle tip damage in the range of 10 microns (1x10-5m). Needles with a higher probability of out-of-the-box damage were associated with more local site reactions, possibly due to greater tissue damage, compounded by IgG stimulating a greater inflammatory response. Patient feedback indicated greater site complications from a faster infusion into a lesser number of sites.

REDUCING INFUSION SITE REACTIONS





Needle Tip Design – Tricuspid Subcutaneous vs Lancet Coring Tip
These images show a lancet cut needle damages more tissue than tricuspid cut and, therefore, may result in more site irritation.

Tricuspid with actual penetration in simulated skin, low damage entry.

Lancet needle actual penetration in simulated skin, more coring for bloodletting, more tissue necrosis.

INFUSION SITE PENETRATION

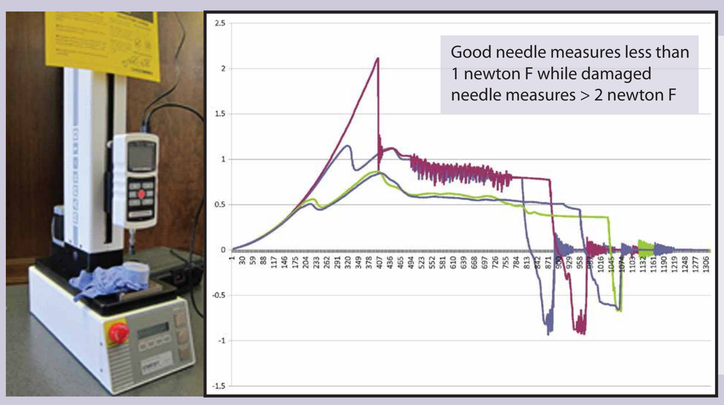
Even though the inner diameters are comparable, the outside diameters are not. A larger needle size can generally be felt by the patient. A 24 gauge needle needs a hole at least 55% larger than 26 gauge.

MULTIPLE NEEDLE SITES

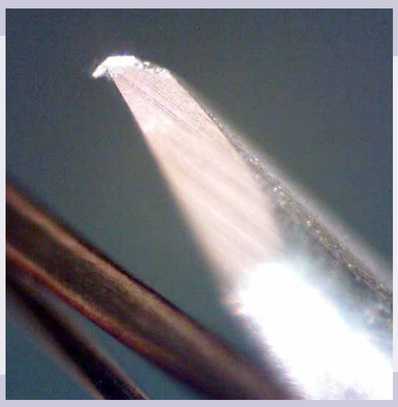
Significance of Equalized Flow

- **Equalized flow reduces selective tissue saturation in sites.**
- **Unequal flow contributes to site complications.**

MEASURING INSERTION FORCE

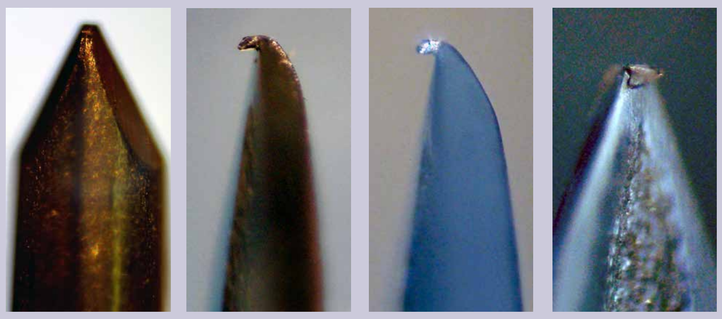


- Damaged needles show correlation with higher measured insertion forces.
- Higher insertion forces are correlated with increased pain, but not one-to-one.



Needle Tip Damage
- Compared with Human Hair
Damage less than 10 microns can be detected by patients.
Even the smallest imperfections can be felt by patients and measured by force data.

IDENTIFYING NEEDLE TIP DAMAGE



Needle tips may be compromised during assembly. X-ray scanning was used to detect damaged needles after final assembly.

Precise Submicron X-ray Scan of Finished Needle Set Assemblies

Needle sets on bed of X-ray

- Sensitivity resolution < 1 micron
- Statistical X-ray scan detects needle damage, length, assembly conformity

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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