Optimization of Patient Comfort During Delivery of Subcutaneous IgG (SCIg)

PRELIMINARY REPORT – November 2017

PURPOSE

The purpose of this summary is to present factual information about SUB-Q needles that will allow clinicians and patients to compare devices from various manufacturers. Needles were compared utilizing the following parameters: type of bevel, length of bevel, surface smoothness, and more importantly penetration force.

BACKGROUND

Needle sharpness is generally considered a key feature of medical needles. Sharper needles offer more comfortable injections, thereby providing both patient and clinician with a more satisfying injection experience.

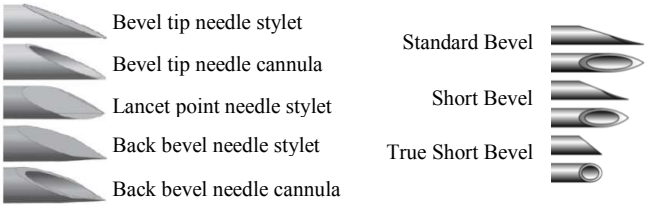
Sharpness depends on several factors including, needle material, manufacturing processes and bevel design. Patient dependent issues that relate to the condition of the skin, repetitious insertions over time and other subjective factors, can play a role in the perception of sharpness. In order to objectively compare needles, penetration force is a means to measure "sharpness" by quantifying the actual force required to puncture through a membrane.

DEFINITIONS (Needle design)

NEEDLE GAUGE & LENGTH

Needle gauge corresponds to the outer diameter of the needle. Given a specific needle gauge, the inner diameter is determined by the wall thickness of the needle. In general, a thinner wall (i.e. larger inner diameter) may present less insertion force as well as a lower resistance to the flow of medication. A thinner wall may make the needle less robust and thus increase their proneness to damage during insertion or handling.

NEEDLE TIP AND BEVEL LENGTH



Needle tips have a direct effect on penetration force and the shape of the incision. Bevel tips should be chosen based on the type of application. Bevel lengths play an important role in the ability of a needle to go through the skin. EMED's *Soft-Glide*® needle is the result of testing and comparing bevel lengths against industry standards.

APPROPRIATE SELECTION OF NEEDLE GAUGE

The appropriate needle gauge and length are determined by a number of factors, including the target tissue, injection formulation, and patient population. For example, subcutaneous tissue requires a different length and gauge than a venipuncture application. Venipuncture requires the use of needles typically as large as 22–21 gauge inserted to depths of 25–38 mm to withdraw milliliters of blood. SCIg has been best managed with 24-27 gauge needles ranging from 4 to 14 mm. Penetration force increases with larger needle diameters.

TRICUSPID DESIGN

In coordination with key opinion leaders, BBraun designed its proprietary Tricuspid design to facilitate the insertion of an indwelling IV catheter. This design was not intended for subcutaneous infusions or a 90 degree insertion. View their technology at: http://www.bbraunusa.com/10720_10735.html.

METHODOLOGY

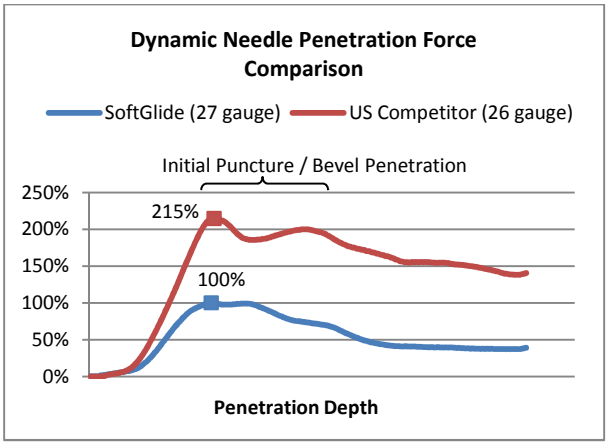
Several needle sharpness studies have documented the use of penetration force of various membranes as a

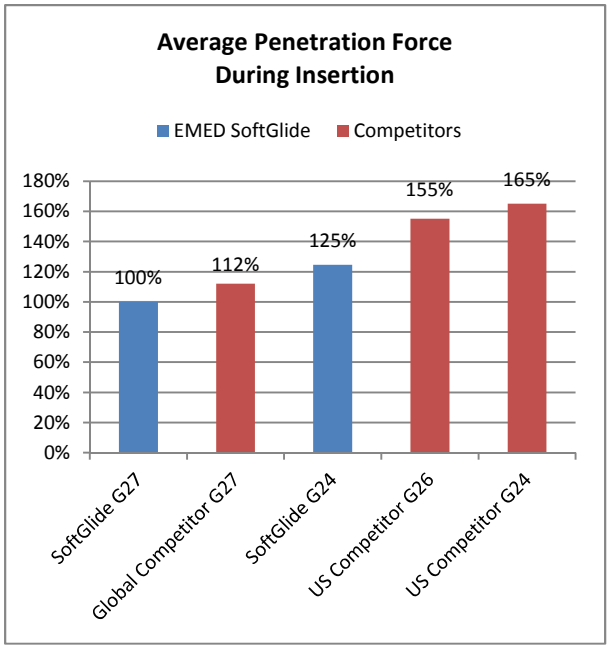
means to establishing needle sharpness and thus perception of pain and comfort. These studies have shown that using a synthetic substrate to measure penetration force studies correlates with less in vivo pain [1].

Needle tip penetration force represents the force required to initially penetrate the membrane.

EMED has conducted multiple tests to compare SUB-Q needles and other market leader needles. The tests are performed according to protocols based on ISO and ASTM standards.

TEST RESULTS





- ➔ Penetration force was plotted for various needles. The forces were sampled dynamically to quantify the effect of the penetration of the needle during the insertion of the tip as well as the rest of the needle.
- ➔ *Soft-Glide*® needles were shown to require the lowest amount of penetration force both during the initial puncture and the rest of the needle insertion
- ➔ SCIg competitors had a significantly lower performance than EMED and needle industry leaders.

CONCLUSIONS

1. Needle bevel design and needle finishing processes are key factors in the sharpness of a needle.
2. *Soft-Glide*® was designed taking all these factors into account. Comparative testing of various designs was conducted to ensure that the selected design offers the best clinical results.
3. EMED *Soft-Glide*® needles outperformed all tested needles. Specific penetration force charts are shown that demonstrate *Soft-Glide*® to require substantially less force during initial puncture and the overall needle insertion compared to SCIG competitors.
4. Needle coating significantly decreases penetration force due to a reduction in the coefficient of friction between the needle surface and the patient's skin.
5. Given a sound needle design and manufacturing process, needle coating significantly increases needle performance and patient comfort.

REFERENCES

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