New Needle Tip –
Less Penetration Force, Less Painful and Preferred*

Overview:
Pain from injection devices is affected by needle length, diameter, needle polishing, lubrication, and needle tip geometry. For the latter, needle tips may vary with the number and angularity of the bevels. Currently, commercially available pen needles have 3-bevels (Fig. 1A). This study was undertaken to evaluate the acceptability and preference of a new 5-bevel needle in patients injecting insulin (Fig. 1B).

Figure 1. 3-bevel tip (1A), 5-bevel tip (1B)

Study Design:
Before the clinical study, the amount of force required to penetrate a human skin surrogate was investigated in the laboratory with multiple currently marketed pen needles. In the clinical study, subjects were adults with diabetes who used insulin pens with BD pen needles. The study had 3 parts; (1st) in clinic blinded paired pen needle insertions (no insulin injections), each pair contained the same gauge/length BD needles - one with 3-bevels, the other with 5-bevels, (2nd) at-home use of 5-bevel pen needles, and (3rd) in clinic non-blinded paired pen needle insertions; each pair contained similar multi-brand needles - one with 3-bevels, the other with 5-bevels.

All paired insertions and insulin injections were performed by the subjects. Prior to home use, subjects were only told that they were evaluating a pen needle with a new design without any information about the needle tip. In the 3rd part, before each insertion the subjects were informed about the different beveled tips.

After each of the paired insertions and home use in Parts 1 and 2, subjects rated the pen needles for overall acceptability. In all 3 parts, comparative pain, insertion ease, comfort and preference were evaluated.

Outcomes:
Laboratory testing - the average penetration force was 23% less with the 5-bevel vs similar 3-bevel pen needles (Fig. 2).

Clinical study - In Part 1, the 5-bevel needle was rated as acceptable by ~ 93% with no differences Vs 3-bevel needles. After home use, the 5-bevel pen needle was also acceptable and rated as less painful, easier to insert, more comfortable and preferable to their usual pen needle = 61-63% vs 7-11%, all p<0.01 (Fig. 3). In Part 3, the 5-bevel pen needle was also rated less painful (p<0.01) and better on the other variables compared to their current and other marketed pen needles = 54-59% vs 21-26% (p=0.01).

Summary: Laboratory testing demonstrated a significant 23% reduction in average penetration force for the new 5-bevel vs current 3-bevel pen needles. When asked to test a new pen needle at home, patients rated the 5-bevel needle significantly more comfortable, easier to insert, preferable, and less painful. These positive results suggest that the 5-bevel needle may help support better acceptance of self-injection therapy. Longer-term studies are recommended.


# Figure modified from original publication.