

Impact of a Modified Needle Tip Geometry on Penetration Force as well as Acceptability, Preference, and Perceived Pain in Subjects with Diabetes

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Abstract

Background:

Multiple factors impact subcutaneous insulin injection pain. Injection devices [e.g., syringe or pen needle (PN)] affect pain due to needle length, diameter, needle polishing and lubrication, and needle tip geometry.

Methods:

We evaluated a modified 5-bevel PN tip in 32 G × 4 mm 31 G × 5 mm and 8 mm PNs vs the equivalent marketed 3-bevel PNs in laboratory penetration force testing, as well as in insulin-taking subjects for overall acceptability, comparative pain, and preference. The clinical tests were done in three ways: paired insertions with the subjects blinded to PN tip geometry, after brief at-home use of 5-bevel PNs, and again with subjects informed about each needle's tip geometry in paired insertions.

Results:

Average penetration force in a skin substitute was 23% lower with the 5-bevel PNs vs similar 3-bevel PNs ($p \leq 0.01$). In blinded testing and after at-home use, patients rated the 5-bevel needle as acceptable. After short-term home use, patients rated the 5-bevel PN less painful and preferable to their usual PN (both $p < 0.01$). In paired, informed testing, the 5-bevel PN was less painful and preferred to subjects' currently used needles ($p \leq 0.01$) and to other marketed PNs ($p < 0.01$).

Conclusions:

Needle tip geometry affects penetration force. When blinded, patients did not distinguish differences in PN tip geometry with fine-gauge PN insertions. A 5-bevel needle tip is perceived as less painful and is preferred by subjects following home use for usual injections. Similar results occurred when patients were informed that they were using a needle with a modified tip.

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Abbreviations: (CI) confidence interval, (PN) pen needle, (SC) subcutaneous, (VAS) visual analog scale

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