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Comparative Glycemic Control, Safety and Patient Ratings for a New 4 mm x 32G Insulin Pen Needle in Adults with Diabetes[1]

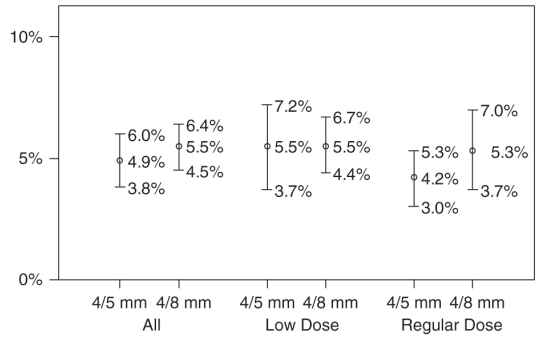
Injection technique is an important aspect of insulin injection therapy, for both consistent insulin delivery and to reduce patient discomfort. It includes (but is not limited to) patient education and factors such as needle length, gauge and injection site; site rotation; use of angled or straight needle insertion; and possible use of a lifted skin-fold by the patient. This study evaluated a new 4 mm x 32G pen needle compared to two marketed pen needles (the 5 mm x 31G and 8 mm x 31G). Outcomes include not only safety and efficacy but also subject-reported injection pain and leakage from injection sites, and overall preference between needles. Efficacy, or equivalent glycemic control, was evaluated with fructosamine. Fructosamine provides a measure of average glycemia over a two to three-week period.

Research design and methods:
Subjects were included in this if diagnosed with type 1 or type 2 diabetes, using an insulin pen at least once per day for ≥2 months, had a BMI 18 to 50 kg/m2 and HbA1c 5.5-9.5%. Subjects were recruited at four clinical centers in the United States. Based on current insulin dosing, subjects were prospectively assigned to an insulin dosing group; low dose (largest single insulin dose allowed ≤20 units) or regular (at least one daily dose of 21-40 units). Qualified subjects had a baseline fructosamine drawn and were randomized to either the 4/5 mm or 4/8 mm comparison group and were provided the study pen needles. The order of pen needle use was also randomized (no subject used all three pen needles). After 21 ± 3 days, subjects returned the 1st study pen needles, had another fructosamine drawn, completed a pain assessment, returned reports of leakage / adverse events and received the alternate pen needles. Three weeks later subjects returned for the final visit, returned the 2nd study pen needles, had his/her final fructosamine drawn, completed a pain assessment, and returned reports of leakage / adverse events. At the end of each study visit, the subjects were also asked to complete a preference survey. Glycemic control would be considered equivalent if the 95% confidence interval for % absolute change in fructosamine was less than 20%.

Results:
Subjects were 56% male, with mean age of nearly 53 years (range 18 to 76); 78% were Caucasian and 63% had type 2 diabetes. Overall, mean BMI was 31.0 kg/m2 (range 20 to 49 kg/m2; 52% of subjects were obese (BMI > 30 kg/m2). Demographic characteristics were evenly distributed throughout all study sub-groups.

Most subjects (65%) had been diagnosed with diabetes for ≥10 years and 58% were treated with insulin for ≥6 years; 7% had used insulin <1 year.

The mean % absolute change in fructosamine was 4.9% (95% confidence interval 3.8, 6.0) between the 4 and 5 mm pen needles, and 5.5% (4.3, 6.4) between the 4 and 8 mm pen needless. There was no statistical difference between the two pen needle groups: the p-values were 0.878 and 0.927, respectively.



Mean % Absolute Change in Fructosamine and 95% confidence interval

No correlation was shown between insulin doses or BMI and change in glycemic control. The 4 mm x 32G pen needle was rated less painful by both study groups (both statistically significant with p <0.02). A numerically smaller proportion of subjects using the 4 mm pen needle reported leakage than with the 5 mm and 8 mm pen needless. Unexplained severe hyper- and hypoglycemic events were infrequent and occurred at similar rates with all three pen needles. Two subjects discontinued the study due to adverse events unrelated to product usage

Needle Length (Number Randomized)	4 mm (*N* = 173)	5 mm (*N* = 89)	8 mm (*N* = 84)
Event			
Hypoglycemia (%)	9 (5.2)	5 (5.6)	4 (4.8)
Hyperglycemia (%)	0 (0)	2 (2.2)	1 (1.2)

Severe Unexplained Hypoglycemic and Hyperglycemic Events Among Randomized Subjects

85% subjects responded to the Preference Survey. Subjects preferred the 4 mm pen needle significantly more than either the 5 mm or 8 mm pen needles (p <0.05;). Approximately four times as many subjects preferred the 4 mm pen needle "a lot more" as did subjects who similarly preferred either of the other two pen needles.

Conclusion
This study has demonstrated equivalent glycemic control with a new 4 mm x 32G pen needle versus two marketed pen needles (5 mm x 31G and 8 mm x 31G) in a group of adult, insulin-requiring patients with diabetes. The 4 mm x 32G pen needle is safe and well tolerated, rated easier to use, did not increase skin leakage, and was preferred by the majority of subjects. These findings support use of a 4 mm x 32G pen needle for subcutaneous insulin injection therapy.

[1] Hirsch LJ, Gibney MA, Albanese J, et al. Comparative glycemic control, safety and patient ratings for a new 4 mm x 32G insulin pen needle in adults with diabetes. Curr Med Res Opin 2010; 26 (6): 1531–1541.
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