The goal of this study was to evaluate the impact of a new extra-thin wall (XTW) pen needle on overall patient preference, ease of injection, thumb button force, dose delivery confidence and perceived time to complete a full dose in individuals with diabetes mellitus (DM). Subjects injected insulin with the KwikPenTM (Eli Lilly and Company, Indianapolis, Indiana), SoloSTAR® (sanofi Aventis U.S. LLC, Bridgewater, New Jersey), and FlexPen® (Novo Nordisk A/S, Bagsvaerd, Denmark) insulin pens.

Methods: First, quantitative laboratory testing of XTW and comparable pen needles was completed with the 3 insulin pens for thumb force, flow rate, and time to deliver medication. Followed by a prospective, randomized, 2-period, cross-over clinical trial with patients aged 35 to 80 years with DM, some with impaired hand dexterity, who injected insulin by pen for ≥2 months; with at least 1 daily dose ≥10 U. Patients who used 4-to 8-mm length pen needles with 31-to 32-G were randomly assigned to use their current pen needle or the same/similar size XTW pen needle at home for 1 week and the other PN the second week. They completed several comparative 150-mm visual analog scales and direct questions at the end of the last period.

Results: In laboratory testing, XTW pen needles had statistically significant better performance for thumb force, flow, and time to deliver medication for all pens combined and each individual pen brand, all p≤0.05. When the BD 4mm x 32G was compared to comparable pen needles, thumb force was reduced by 62%, flow rate increased by 149%, and time to deliver medication reduced by 60%. In the clinical study, 216 subjects were randomized (SoloSTAR, 80; FlexPen, 77; KwikPen, 59), with 198 evaluable. Baseline characteristics were mean age of 60.8 years, insulin pen use duration of 4.3 years, and mean total daily dose of 75.1 units (range 10–420 units). Approximately 50% were female, 82% white, 14.8% black, and 90% type 2 DM. The 8mm pen needle was used by 49.5% and 12% used the 4mm length. Compared to usual pen needles, the XTW pen needles were rated as being significantly more preferable (68%), requiring less thumb force (61%), less painful (64%), easier to insert (64%), providing greater confidence in full dose delivery (52%) and less time to inject dose (49%), all p<0.001.

Results were similar for each of the 3 pens, those with impaired hand dexterity, and for all users of 4-mm pen needles.

Skin leakage and insulin dripping from the needle tip were rated as significantly less frequent with the XTW pen needles (p<0.05). In addition, laboratory testing demonstrated there are no differences in bending or breakage between thin wall and the XTW pen needles.

Conclusions: Compared to usual pen needle, extra thin-walled pen needles with improved insulin flow were preferred, rated as requiring less thumb force, less painful, easier to insert, provided greater confidence in giving a full dose and less time to deliver the dose.