Enlite subcutaneous glucose sensor was previously evaluated in adults and children and shown to be accurate for 6 days, durable, and acceptable to patients and parents/caregivers.

A pivotal 6-day trial in adults was conducted at 7 US investigational centers. Sensors were well-inserted and taped. Accuracy was evaluated vs. frequently-sampled YSI plasma glucose values. Hypoglycemia and hyperglycemia were induced on days 1 (immediately after initial calibration), day 3, and day 6. Patient satisfaction with Enlite was also evaluated with a 7-point Likert-type questionnaire.

Adults with type 1 (n=65) or type 2 (n=25) diabetes (mean age 44, range 18-71) were either 1 or 2 sensors on their abdomens for 6 days. Accuracy was demonstrated for 6 days at all glucose concentrations despite including sparse and uneven calibration events. Valid sensor readings were obtained soon after insertion and reflected blood glucose values with minimal lag time. Patient satisfaction surveys indicated that the Enlite sensor was easy to insert, comfortable to wear, and easy to remove. There were no device-related adverse events.

The Enlite sensor is accurate, durable, comfortable, safe, and easy to use. Improvements in continuous glucose sensing should expedite development of semi-automated insulin delivery features in modern pumps.

Accuracy for 6 Days

During the FST, sensors were calibrated either 3-4 times per day ("actual use calibration") or every 12 hours ("minimal calibration"). During home use (days 2, 4, and 5), sensors were calibrated 3-4 times per day.

Enlite vs. Sot-sensor

Accuracy during FST, by positive or negative YSI glucose rate of change (ROC) between SMBG calibrations.

Accuracy for 6 Days

Accuracy during FST, by positive or negative YSI glucose rate of change (ROC) between SMBG calibrations.

Accuracy during FST, actual use calibration, by day (cal. frequency 2.8±0.9/d)

Accuracy during FST, actual use calibration, by day (cal. frequency 2.8±0.9/d)

Accuracy during FST, minimal calibration, by day (cal. frequency 1.2±0.9/d)

Accuracy during FST, minimal calibration, by day (cal. frequency 1.2±0.9/d)

Conclusions and Implications

- The Enlite sensor provides accurate readings for 6 days in adults with either type 1 or type 2 diabetes, with an overall MARD of 13.6%. This accuracy was achieved under circumstances in which:
  - Calibrations were performed at any time
  - Glucose concentrations were changing rapidly
  - Many glucose concentrations were high or low
- Enlite sensor glucose readings remained accurate at slow, moderate, and rapid rates of glucose concentration change.
- The Enlite sensor remained accurate even with minimal calibrations.
- Survey responses showed that the Enlite sensor was easy to use, easy to insert, and comfortable to wear.
- Enhanced sensor accuracy should be sufficient to allow development of automated functions that will lead to the artificial pancreas.