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ORIGINAL ARTICLE

A Human Pilot Study of the Fluorescence Affinity Sensor for Continuous Glucose Monitoring in Diabetes

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Abstract

Objective:

We report results of a pilot clinical study of a subcutaneous fluorescence affinity sensor (FAS) for continuous glucose monitoring conducted in people with type 1 and type 2 diabetes. The device was assessed based on performance, safety, and comfort level under acute conditions (4 h).

Research Design and Methods:

A second-generation FAS (BioTex Inc., Houston, TX) was subcutaneously implanted in the abdomens of 12 people with diabetes, and its acute performance to excursions in blood glucose was monitored over 4 h. After 30–60 min the subjects, who all had fasting blood glucose levels of less than 200 mg/dl, received a glucose bolus of 75 g/liter dextrose by oral administration. Capillary blood glucose samples were obtained from the finger tip. The FAS data were retrospectively evaluated by linear least squares regression analysis and by the Clarke error grid method. Comfort levels during insertion, operation, and sensor removal were scored by the subjects using an analog pain scale.

Results:

After retrospective calibration of 17 sensors implanted in 12 subjects, error grid analysis showed 97% of the paired values in zones A and B and 1.5% in zones C and D, respectively. The mean absolute relative error between sensor signal and capillary blood glucose was 13% [±15% standard deviation (SD), 100–350 mg/dl] with an average correlation coefficient of 0.84 (±0.24 SD). The actual average "warm-up" time for the FAS readings, at which highest correlation with glucose readings was determined, was 65 (±32 SD) min. Mean time lag was 4 (±5 SD) min during the initial operational hours. Pain levels during insertion and operation were modest.

Conclusions:

The *in vivo* performance of the FAS demonstrates feasibility of the fluorescence affinity technology to determine blood glucose excursions accurately and safely under acute dynamic conditions in humans with type 1 and type 2 diabetes. Specific engineering challenges to sensor and instrumentation robustness remain. Further studies will be required to validate its promising performance over longer implantation duration (5–7 days) in people with diabetes.

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Abbreviations: (ConA) concanavalin A, (FAS) fluorescence affinity sensor, (MARE) mean absolute relative error, (NAMSA) North American Science Associates, (R) correlation coefficient, (SD) standard deviation

Keywords: concanavalin A, fluorescence, fluorescence resonance energy transfer, optical affinity glucose sensor

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