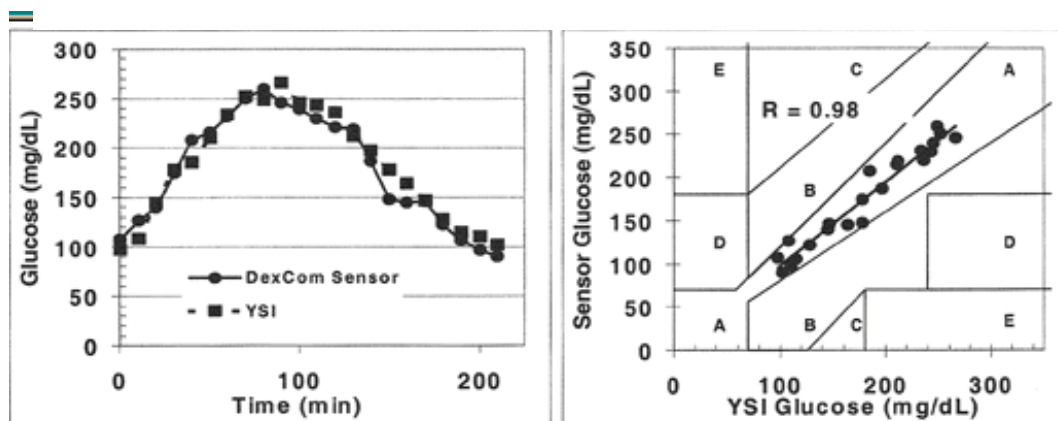


Long-Term Continuous Glucose Monitor in Subcutaneous Tissue; Accuracy Results from a 25-Subject Study

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The clinical reality of obtaining "real time" glucose values without fingersticks could greatly improve patient compliance and provide euglycemia. A novel, long-term implantable sensor that continuously monitors glucose and transmits data to a portable receiver was tested for up to 7 months in humans. The small, cylindrical sensor was implanted into the subcutaneous tissue under local anesthesia. The electrochemical sensor used a 3-electrode system covered with proprietary membranes. The 2-phase study examined 25 subjects with Type 1 diabetes: 19 in Phase 1 and 6 more in Phase 2. Phase 2 incorporated design improvements. Glucose Tracking Studies (GTS) were performed between days 49 and 96 by giving an oral glucose load and obtaining blood samples every 10-15 minutes by SMBG (TheraSense), HemoCue, and YSI. After the subjects reached 250 mg/dL, insulin lispro was self-administered to lower glucose levels. Sensor data were compared with reference glucose methods using linear regression and Clarke Error Grid Analysis. Five of the Phase 1 subjects and all 6 of the Phase 2 subjects were determined to have clinically functional sensors. Mean R-values were 0.94 with a range from 0.80-0.99, and 100% of the points were in the A and B region of the Clarke grid. These results demonstrate a high correlation between the sensor and reference blood glucose values. This novel, long-term subcutaneous glucose sensor is accurate compared with reference glucose values and has potential to improve glycemic control in patients with diabetes.



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