

A Randomized Controlled Study of a Transcutaneous, Real-Time Continuous Glucose Sensor Demonstrates Improvement in Glycemic Control.

L Jovanovic, MD¹, H Zisser, MD¹, S Schwartz, MD², T Bailey, MD³ and R Kaplan, MD⁴.
¹Santa Barbara, California, United States; ²San Antonio, Texas, United States; ³Escondido, California, United States and ⁴Concord, California, United States.

The safety and efficacy of a short-term real-time continuous glucose sensor (DexCom Inc.) were evaluated in 91 subjects with type 1 or type 2, insulin-requiring diabetes at 4 Sites. The Sensor wirelessly transmitted glucose data to a hand-held unit. Subjects wore a Sensor in the abdominal s.q. tissue for 3 consecutive 72-hr periods. The Control Group (n=44) was blinded to glucose data for all 3 periods. The Display Group (n=47) was blinded during Period 1 and unblinded in Periods 2 and 3. The unblinded device displayed the current glucose value, 1-, 3 and 9-hr trend graphs, and provided high and low glucose alerts (set at 200 mg/dl and 80 mg/dl) and a low alarm (55 mg/dl).

Of the 6767 matched BG/Sensor values prospectively analyzed, 95.4% fell in the Clarke Error Grid A+B zones, 2.1% in the D zone, and 0.0% in the E zone. The median Absolute Relative Difference was 15.9%.

The trial showed improvement in glycemic profiles (less hypo- and hyperglycemia) with use of the device with no guidance on therapeutic adjustments from physicians. Comparing the Control to the Display Group, the Display Group spent 21% less time low (<55 mg/dl), 23% less time high (>240 mg/dl), and 26% more time in the target glucose range (81-140 mg/dl) (p<.0001). Comparing Period 1 (Blinded) with Period 3 (Unblinded) in the Display Group, subjects improved glycemic control within just 6 days by decreasing highs 15%, decreasing lows 9% and increasing time in the target range 16% (p<.001).

If the Control Group were provided Sensor data during use, the trend screen, low alert, and low alarm would have predicted 95% of the ≤55 mg/dl blood glucose events. The Subjects would have been warned on average 2.5 times preceding the ≤55 mg/dl fingerstick within 47±51 minutes.

There were no hypoglycemia events requiring assistance in the Display Group, but 3 hypoglycemia events requiring assistance in 2 subjects in the Control Group.