

Analysis: Accuracy Performance of the Medtronic NexSensor for 6 Days in an Inpatient Setting Using Abdomen and Buttocks Insertion Sites

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Abstract

In an article in this issue of *Journal of Diabetes Science and Technology*, Peoples and colleagues address the issue that, while continuous glucose sensors have been shown to improve hemoglobin A1c, they are still fraught with concerns regarding accuracy and flexibility in sensor placement. Their study aimed to evaluate whether NexSensor, an improved version of the already commercially available Sof-Sensor, can be used for 6 days instead of the 3 days approved for Sof-Sensor in the United States. Also, the article aims to compare the accuracy of wearing the sensor in the abdomen versus the buttocks, given that this offers more flexibility than the approved labeling for Sof-Sensor, which is only in the abdomen. The study demonstrated that NexSensor is both safe and accurate for 6 days at both insertion sites. There was no statistically significant difference between the sites. As far as improved accuracy, the authors find evidence in favor of NexSensor as compared to Sof-Sensor, although this evidence is preliminary and is not backed by statistical significance measures.

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Introduction

Evidence from randomized controlled trials strongly supports the use of real-time continuous glucose monitors (CGMs) in routine clinical care of people with type 1 diabetes, which leads to a 0.53% decrease, on average, in hemoglobin A1c.¹⁻³ Additional supportive data come from trials in several specific patient groups, including pregnant women⁴ and patients with cystic fibrosis.⁵ Today, continuous glucose monitoring is becoming the standard of care for patients with type 1 diabetes; however, sensors are still sometimes uncomfortable to wear, and accuracy of

the sensors, particularly at high and low glucose levels and at times of rapid change, are still important issues that need to be improved.

The study presented in this issue of *Journal of Diabetes Science and Technology* by Peoples and colleagues⁶ aims to address some of these issues. NexSensor has a form factor identical to Sof-Sensor (already commercially available), and it can even use the same insertion device and CGM receiver as Sof-Sensor; however, NexSensor has a few

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Abbreviations: (ARD) absolute relative difference, (CGM) continuous glucose monitor

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features that are meant to improve the operating life and reliability between sensors. In the United States, Sof-Sensor is approved for use for no more than 3 days at a time, and it is approved for use only at the abdomen. This study aimed to show that NexSensor could be worn at the abdomen as well as in the buttocks. It also aimed to show that it is safe for use for 6 days, instead of 3 days.

The subjects enrolled in the study were 18 to 75 years of age and had type 1 diabetes treated with an insulin pump or multiple daily injections of insulin for at least 3 months. Subjects wore the NexSensor on the abdomen and buttocks simultaneously. Sensors inserted at the abdomen site were connected to a real-time CGM system (Guardian REAL-Time System, Medtronic), and sensors inserted on the buttocks site were connected to a CGM recorder (CGMS iPro™, Medtronic).

All subjects were randomized to a one-time 12 h frequent blood sampling test on one of the six days of sensor use, where plasma glucose values were measured every 15 min. These measurements were later compared with the sensor values collected. On this day, the subjects' glucose was either allowed to fall below 70 mg/dl or decreased with insulin in order to check the accuracy and precision at low levels. A meal was then given, and the glucose values were allowed to rise above 250 mg/dl to check accuracy and precision at higher glucose values.

The study enrolled 63 subjects, of which 61 completed the study. Two subjects who withdrew requested to be withdrawn; they did not discontinue because of an adverse event.

Several different analyses were extracted from the data. A precision analysis, referring to the repeatability or reproducibility of the measurement, compared the values derived from the abdomen and buttocks sensors, using the abdomen sensor as the reference. The mean agreement rate, which was found to be within 20% (or 20 mg/dl in the 40–80 mg/dl range), was 72.48%.

The accuracy analysis was derived from a dataset of paired sensor and reference values obtained during the frequent-sampling visits. Sensor and reference values were restricted to 40–400 mg/dl to correspond to the sensor's performance range. The mean agreement rate represented the proportion of sensor values that were within 20% (or 20 mg/dl in the 40–80 mg/dl range) of corresponding reference values (the blood samples drawn every 15 min). The mean agreement rate was 75.5%

(95% confidence interval, 69.5, 81.4) at the abdomen site and 73.8% (68.8, 78.8) at the buttocks site, with no statistically significant difference between the two sites ($p = .78$).

Another way of evaluating accuracy was by computing the mean absolute relative difference (ARD) and the median ARD between the sensor and reference values, relative to the reference value. The overall median ARD was 12.3% at the abdomen site and 11.5% at the buttocks site. The overall mean ARD was 17.1% at the abdomen site and 16.5% at the buttocks site. Again, there was no overall statistical difference between the two sites for either median or mean.

Another way to assess accuracy is to do the Clarke error grid analysis. This analysis serves to quantify the clinical accuracy of blood glucose meters. A scatter plot of the reference glucose values and the values obtained from the continuous glucose sensor fall on a grid into one of five regions. Region A includes those values within 20% of the reference value. Region B contains points that are outside of 20% but would not lead to inappropriate treatment. Region C includes those points leading to unnecessary treatment. Region D contains those points indicating a potentially dangerous failure to detect hypoglycemia or hyperglycemia. Region E includes those points that would confuse treatment of hypoglycemia for hyperglycemia or vice-versa. In this study, over 90% of paired sensor-reference values were in the A and B zones of the Clarke error grids at the abdomen and buttocks (respectively, 93% and 94%), with no statistically significant difference between the two sites ($p = .62$).

The sensor was equally accurate on day 6 as well as day 2, as seen by the fact that the ARD was consistent from days 2 through 6 of sensor wear. Day 1 of sensor wear had a higher ARD than other days, possibly due to calibration issues.

People and colleagues⁶ concluded that, overall, there is no statistically significant difference between the abdomen and buttocks, which offers the user the possibility of using either site. The authors also found that the sensor is safe and accurate to wear for 6 days in a row.

The authors also claim improvements in accuracy over Sof-Sensor. Although it is stated that the ARD was 3% smaller in NexSensor than in Sof-Sensor, it is not clear from the article that this is statistically significant or that it is clinically relevant. Furthermore, the Clarke error grid analysis for NexSensor (94%) was actually lower than in the regulatory study for Sof-Sensor (96%),

although, when looking at zone A alone, NexSensor was higher (71%, combined sites) as compared to Sof-Sensor (62%). Given the discrepancies, the fact that NexSensor was conducted at two sites, while it is not specified which site was used for Sof-Sensor, and the fact that no statistical significance is mentioned, it seems premature to determine which site is more accurate. A focused comparative study is needed in order to determine which sensor is more accurate.

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