

Simultaneous Device Wear May Disclose Disparate Continuous Glucose Monitoring Performance

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Introduction

Various approaches have been considered to measure the accuracy and utility of continuous glucose monitors, and to compare results between monitors. Because of the dynamic rather than static nature of continuous monitors, many evaluation methods, such as the original Clarke error grid, Pearson correlation, and area under the curve (AUC) have been criticized as being inaccurate or inappropriate tools.^{1,2} We desired a more direct and practical method for comparing continuous monitor results, and for determining an appropriate device for individual users within the clinical setting.



Both sensors show the current 3 hr glucose trend with a BG axis of 0 to 400. An Ultra reading at the time was 73 mg/dl.

Today's continuous monitors are different from prior CGMS systems in that:

- current estimated blood glucose values are openly displayed to users.
- adjustable alerts are available to warn users when their glucose crosses a low or high threshold.

With an open display, the accuracy and timeliness of displayed readings and warnings become quite important. If users overly trust the monitor's readings, they may make inappropriate clinical decisions. Neither of these monitors is approved for clinical use independent of a meter test. In comparing sensors, the most important decision for many users is whether the sensor will accurately warn of hypoglycemia, and continuous monitors have had difficulty doing this.³

Fortunately, when two different sensors are worn at the same time, the sensors can be set with identical high and low alerts to determine which one provides the most appropriate information. This study utilized the internal warning system of the monitors, combined with frequent daily fingerstick tests and additional fingerstick tests done when a disagreement occurred between two displayed readings to test the appropriateness of warnings and the accuracy of displayed readings.

Methods

One individual (59 yo male with IDDM and recent A1c of 6.4% on an insulin pump) volunteered to wear two CGM devices from different manufacturers and to compare their displayed results with simultaneous readings from a One Touch Ultra meter. The readings generally reflect real life circumstances, although hypoglycemia and hyperglycemia were at times voluntarily induced to further test the accuracy and responsiveness of the sensors.

The low alert was set to 80 mg/dl and high alert to 160 mg/dl in each monitor. When an alert was sounded by one of the sensors, readings from both sensors were recorded and a fingerstick test with an Ultra meter was obtained. Routine testing was also done with results from both sensors recorded at those times. When a significant difference in values was noted between the sensors, such as greater than 30 mg/dl, an additional fingerstick test was done. Each sensor was operated as directed. Each required 2 calibration tests per day and these calibrations rarely occurred at the same time. Calibration was performed from the same Ultra meter. On some days, 1 to no more than 2 additional calibrations were done for both sensors simultaneously, averaging about 1 extra calibration per day per sensor.

How Different From The Ultra Was Each Sensor? Difference in BG:	Sensor A	Sensor B
0-9 mg/dl	54	21
10-19 mg/dl	42	28
20-29 mg/dl	15	23
30-39 mg/dl	9	19
40-49 mg/dl	3	17
50-59 mg/dl	4	12
60-129 mg/dl	2	9

129 readings for each sensor

Results

For this individual, Sensor A performed significantly better than Sensor B. It was first to detect BGs less than 80 in 13 instances versus 1 for Sensor B with 4 ties. For detection of readings above 160 mg/dl, it was first in 12 instances versus 0 for Sensor B with 4 ties. There were 6 glucose readings greater than 50 mg/dl difference from Ultra readings for Sensor A, and 21 for Sensor B.

For percentage difference for total BG readings at different BG ranges, Sensor A averaged within 2% of Ultra readings throughout the 0 and 240 mg/dl range and read 8.5% low above 240 mg/dl with only 7 Ultra readings in this range. Sensor B's readings were 36.5% high for values below 80 mg/dl, within 2% between 81 and 160, 21.5% low between 161 and 240, and 30.7% high above 240 mg/dl.

BG Range	# of Readings	Avg. Ultra BG	Sensor A	Sensor B	Diff in mg/dl Diff in %	Diff in mg/dl Diff in %
0-80 mg/dl	22	66.1	-0.26	-0.39%	24.13	36.50%
81-160 mg/dl	73	115.5	-0.21	-0.18%	2.12	1.84%
161-240 mg/dl	25	195.9	-3.4	-1.74%	-42.04	-21.50%
>240 mg/dl	7	287	-24.29	-8.46%	-88	-30.70%

When sensors differed in value, only rarely was this due to a delay in response. On occasion, Sensor B would ultimately catch up to the full drop or rise displayed by Sensor A, usually 15 to 60 minutes later. More often, however Sensor B never achieved the full drop or rise. This can be noted by the difference in SD and by the results in the paragraph above.

Mean average deviation:

Sensor A: 15.9%
Sensor B: 31.4%.

Conclusions

- Continuous monitors may differ in performance in a single individual.
- Failure or delay in recognition of hypoglycemic or hyperglycemic trends may be clinically significant.
- Side-by-side performance evaluations of monitoring devices may be important to understand the potential for missed or delayed recognition of out-of-range glucose values.
- Further studies are required to determine the characteristics that will predict which CGMS device will provide optimum outcomes in an individual patient.

References:

- Craig Kollman et al. Limitations of Statistical Measures of Error in Assessing the Accuracy of Continuous Glucose Sensors. Diabetes Technology & Therapeutics Vol. 7, No. 5, 665-672, Oct 2005
- Diabetes Technology & Therapeutics. Dec 2005, Vol. 7, No. 6: 849-862DirectNet Study Group: Accuracy of the GlucoWatch G2 Biographer and the CGMS during hypoglycemia. Diabetes Care 27:722-726, 2004
- Endocrine Practice: Volume 10, Number 4 / July / August 2004, pgs 324-329

Color Scheme

Sensor was first to detect reading less than 80 mg/dl
Sensor was first to detect reading more than 160 mg/dl
Reading differed by more than 50 mg/dl from Ultra

Ultra BGs-- Sequential In Time

Date	Time	Ultra	Sensor A	Sensor B
29-Sep	17:58	128	81	111
29-Sep	18:08	130	127	129
29-Sep	18:48	135	118	150
29-Sep	19:19	74	66	112
29-Sep	19:36	56	54	95
29-Sep	19:52	58	50	65
29-Sep	21:43	69	79	69
30-Sep	0:11	94	110	138
30-Sep	0:55	163	163	163
30-Sep	1:32	201	122	220
30-Sep	4:46	114	63	166
30-Sep	11:27	225	144	224
30-Sep	15:17	189	129	111
30-Sep	16:14	82	83	104
30-Sep	16:37	60	67	90
30-Sep	20:08	129	131	89
30-Sep	21:37	149	96	110
1-Oct	11:19	190	139	191
1-Oct	15:37	75	77	76
1-Oct	16:46	95	116	74
1-Oct	19:33	88	97	46
1-Oct	20:29	57	66	44
2-Oct	11:27	105	128	112
2-Oct	15:18	125	126	178
2-Oct	20:12	153	153	150
3-Oct	20:31	165	52	120
3-Oct	21:18	60	54	84
3-Oct	21:34	51	43	78
3-Oct	22:34	91	77	82
4-Oct	8:13	125	126	125
4-Oct	10:19	168	198	122
4-Oct	12:09	129	131	161
4-Oct	14:07	92	105	140
4-Oct	14:29	87	77	111
4-Oct	16:08	176	199	176
4-Oct	20:24	199	181	210
4-Oct	21:11	122	115	131
4-Oct	22:06	205	211	76
5-Oct	12:52	127	126	128
6-Oct	13:34	97	80	110
6-Oct	16:39	81	78	89
6-Oct	16:57	91	95	74
7-Oct	0:11	149	153	104
7-Oct	8:29	86	80	98
7-Oct	11:27	68	71	80
7-Oct	18:58	118	122	120
7-Oct	20:55	81	82	80
8-Oct	8:33	118	122	130
8-Oct	11:15	212	216	203
8-Oct	12:39	129	141	141
8-Oct	13:09	130	140	130
8-Oct	13:42	217	210	164
8-Oct	14:26	103	141	106
8-Oct	16:02	146	128	96
8-Oct	18:02	187	176	368
9-Oct	8:37	102	86	123
9-Oct	8:55	87	80	116
9-Oct	16:22	80	82	104
9-Oct	22:17	211	208	164
9-Oct	22:17	211	208	164
10-Oct	8:38	150	134	152
10-Oct	15:51	85	82	80
10-Oct	17:17	205	219	178
11-Oct	3:23	297	230	188
11-Oct	19:26	78	84	88

Average	131.54	129.94	124.68
SD	68.06	59.81	41.38
Avg. Deviation	47.02	45.28	31.92
1st detection of BG < 80	15 (4%)	1 (1%)	15 (12%)
Purple = values differ over 50 mg/dl			
*Purple around cell indicates a low sensor was placed			

Ultra BGs -- Low To High

Date	Time	Ultra	Sensor A	Sensor B
3-Oct	21:24	51	43	76
29-Sep	19:36	56	54	95
1-Oct	20:29	57	66	44
1-Oct	19:52	58	50	65
1-Oct	16:15	58	40	78
7-Oct	11:39	59	55	78
30-Sep	16:37	60	67	90
3-Oct	21:19	60	66	76
13-Oct	13:53	63	43	80
16-Oct	11:14	63	78	112
16-Oct	16:03	63	93	44
19-Oct	19:51	65	62	80
4-Oct	14:29	67	77	116
7-Oct	11:27	68	71	89
13-Oct	11:42	68	78	114
29-Sep	21:43	69	79	69
13-Oct	11:39	73	83	122
30-Sep	19:19	74	69	112
1-Oct	15:37	75	77	76
13-Oct	13:39	76	77	80
11-Oct	19:26	78	84	88
9-Oct	16:52	80	82	104
15-Oct	14:54	80	81	112
7-Oct	20:55	81	82	88
14-Oct	13:48	81	79	103
14-Oct	17:38	81	77	112
30-Sep	16:14	82	87	104
14-Oct	8:01	82	107	108
14-Oct	19:32	82	86	86
16-Oct	17:18	83	48	70
14-Oct	16:08	85	109	104
16-Oct	15:35	85	78	92
1-Oct	15:34	86	92	114
13-Oct	14:05	86	69	78
8-Oct	8:55	87	80	116
1-Oct	19:33	88	97	46
7-Oct	8:29	88	80	98
3-Oct	22:34	91	77	82
4-Oct	14:07	92	104	140
13-Oct	13:36	92	83	94
15-Oct	14:39	92	80	144
8-Oct	15:39	93	78	89
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11-Oct	21:12	97	134	98
13-Oct	12:33	99	74	89
15-Oct	0:01	99	92	120
11-Oct	16:36	100	94	80
16-Oct	12:59	100	114	142
8-Oct	16:57	101	96	74
9-Oct	8:37	102	86	123
8-Oct	15:38	103	141	120
14-Oct	11:17	108	105	112
14-Oct	17:03	108	108	112
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8-Oct	16:57	101	96	74
9-Oct	8:37	102	86	123
8-Oct	15:38	103	141	120
14-Oct	11:17	108	105	112
14-Oct	17:03	108	108	112
14-Oct	11:17	108	105	112
14-Oct	17:03	1		