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.

Today's continuous monitors are different from prior CGMS systems in that:
A) current estimated blood glucose values are openly displayed to users.
B) 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
50-69 mg/dl	4	12
60-129 mg/dl	2	9
	129 readings for each sensor	

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.

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 3 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 differece 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.

Avg. Diff. in mg/dl and % between Sensor and Ultra Meter at Different BG ranges

		Avg. Ultra BG	Sensor A		Sensor B	
BG Range	**# of Readings**		**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	195.8	-3.4	-1.74%	-42.04	-21.50%
241 or over 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

1. Continuous monitors may differ in performance in a single individual.
2. Failure or delay in recognition of hypoglycemic or hyperglycemic trends may be clinically significant.
3. 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.
4. Further studies are required to determine the characteristics that will predict which CGMS device will provide optimum outcomes in an individual patient.

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

BGs Sorted Sequentially by Time of Test

Date	Time	Ultra	Sensor A	Sensor B
29-Sep	17:58	128	83	112
29-Sep	18:06	130	127	170
29-Sep	18:48	135	118	150
29-Sep	19:19	74	69	112
29-Sep	19:34	56	54	95
29-Sep	19:52	58	50	65
29-Sep	21:43	69	78	96
30-Sep	0:11	94	110	138
30-Sep	0:55	231	163	158
30-Sep	1:32	201	122	220
30-Sep	8:46	114	63	166
30-Sep	11:27	229	168	224
30-Sep	15:17	181	160	112
30-Sep	16:14	82	87	104
30-Sep	16:37	60	67	90
30-Sep	20:08	129	131	80
30-Sep	21:37	149	160	110
30-Sep	22:52	205	217	118
1-Oct	10:24	86	60	114
1-Oct	11:19	150	136	168
1-Oct	15:37	75	77	76
1-Oct	16:46	95	116	74
1-Oct	19:33	88	97	46
1-Oct	20:20	57	68	44
2-Oct	23:14	105	128	112
2-Oct	7:25	278	294	272
2-Oct	11:27	152	176	122
2-Oct	15:18	125	126	176
2-Oct	23:12	153	183	156
3-Oct	20:31	96	99	128
3-Oct	21:18	60	54	84
3-Oct	21:56	51	43	78
3-Oct	22:34	91	77	82
4-Oct	9:13	125	169	100
4-Oct	10:19	168	195	122
4-Oct	12:59	129	131	162
4-Oct	14:07	92	104	140
4-Oct	14:29	67	77	116
4-Oct	19:58	176	191	212
4-Oct	20:24	159	181	210
5-Oct	7:11	122	115	106
5-Oct	22:06	205	211	76
6-Oct	12:52	127	108	136
6-Oct	13:34	97	80	110
6-Oct	15:39	93	78	98
6-Oct	16:57	101	96	74
7-Oct	0:11	149	153	104
7-Oct	8:29	88	80	98
7-Oct	11:27	68	71	80
7-Oct	11:39	59	55	76
7-Oct	20:55	81	82	80
8-Oct	8:33	118	122	120
8-Oct	11:15	212	218	202
8-Oct	12:39	129	141	144
8-Oct	13:09	149	162	114
8-Oct	13:42	217	210	164
8-Oct	15:38	103	141	126
8-Oct	18:02	146	128	96
8-Oct	18:52	187	176	136
9-Oct	8:37	102	86	128
9-Oct	9:55	87	80	116
9-Oct	16:22	80	82	104
9-Oct	20:17	211	250	184
9-Oct	20:42	273	249	196
9-Oct	22:17	341	344	358
10-Oct	8:38	150	134	162
10-Oct	15:51	65	62	80
10-Oct	17:17	205	219	172
10-Oct	3:23	297	230	188
11-Oct	19:26	78	84	88
11-Oct	19:36	100	94	80
11-Oct	21:12	97	134	98
12-Oct	11:30	171	148	138
12-Oct	11:48	181	172	160
12-Oct	12:24	112	90	148
12-Oct	12:35	92	53	144
12-Oct	13:58	94	80	106
12-Oct	19:03	166	166	118
12-Oct	19:53	136	107	114
12-Oct	20:45	128	133	108
12-Oct	21:54	139	167	108
13-Oct	11:30	73	93	122
13-Oct	11:42	68	78	114
13-Oct	12:33	99	74	98
13-Oct	13:39	76	77	90
13-Oct	13:53	63	43	80
13-Oct	14:05	86	69	76
13-Oct	15:21	137	139	124
13-Oct	17:07	142	158	108
13-Oct	20:16	138	123	108
13-Oct	20:41	134	137	140
14-Oct	8:01	82	107	108
14-Oct	9:39	119	161	98
14-Oct	10:31	112	148	116
14-Oct	10:58	85	109	104
14-Oct	11:17	108	105	98
14-Oct	11:28	157	163	102
14-Oct	11:50	218	231	130
14-Oct	12:17	164	219	164
14-Oct	12:40	158	192	150
14-Oct	13:17	117	119	134
14-Oct	13:48	81	79	102
14-Oct	15:40	252	234	142
14-Oct	16:08	282	280	144
14-Oct	17:03	286	276	166
14-Oct	17:58	208	206	140
14-Oct	19:32	82	80	80
14-Oct	21:43	137	123	92
15-Oct	10:01	99	92	120
15-Oct	14:39	92	80	144
15-Oct	14:54	80	61	112
15-Oct	19:26	109	93	74
16-Oct	7:38	81	77	112
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16-Oct	16:15	58	40	78
16-Oct	17:18	83	48	70
16-Oct	18:05	108	110	116
16-Oct	18:56	154	163	140
16-Oct	19:20	209	221	152
16-Oct	23:09	173	175	152
17-Oct	8:20	150	141	134
17-Oct	9:55	227	217	164
17-Oct	12:33	166	178	130
17-Oct	13:06	192	199	152
17-Oct	13:27	192	197	154
Average		131.54	129.94	124.68
SD		58.56	59.81	41.38
Avg. Deviation		47.02	49.28	31.92
1st detection of BG < 80			13 (+3)	1 (+3)
1st detection of BG > 160			12 (+4)	0 (+4)

Purple = values differ over 50 mg/dl

Square around cell indicates a new sensor was placed

Ultra BGs -- Low To High

BGs Sorted by Ultra Result -- Low to High

Date	Time	Ultra	Sensor A	Sensor B
3-Oct	21:24	51	43	78
29-Sep	19:34	56	54	95
1-Oct	20:29	57	68	44
29-Sep	19:52	58	50	65
16-Oct	16:15	58	40	78
7-Oct	11:39	59	55	76
30-Sep	16:37	60	67	90
3-Oct	21:18	60	54	84
13-Oct	13:53	63	43	80
16-Oct	11:14	63	78	112
16-Oct	16:03	63	53	84
10-Oct	15:51	65	62	80
4-Oct	14:29	67	77	116
7-Oct	11:27	68	71	80
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29-Sep	21:43	69	79	96
13-Oct	11:30	73	93	122
29-Sep	19:19	74	69	112
1-Oct	15:37	75	77	76
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30-Sep	16:14	82	87	104
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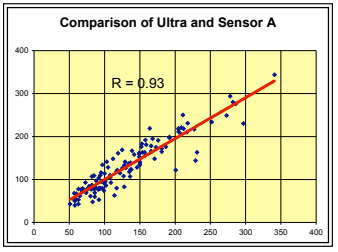

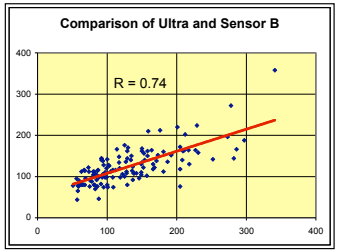

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