Accuracy Evaluation of the FreeStyle Freedom Lite, Accu-Chek Performa, OneTouch Ultra and OneTouch Vita Systems.

Background*:* The minimum acceptable accuracy for results produced by a blood glucose monitoring system according to the current version of the ISO 15197 standard, created in 2003 is: 95 % of the individual glucose results shall fall within ± 0.83 mmol/L (15 mg/dL) of the results of the manufacturer's measurement procedure at glucose concentrations < 4.2 mmol/L (< 75 mg/dL) and within ± 20 % at glucose concentrations ≥ 4.2 mmol/L (≥ 75 mg/dL). The ISO standard is undergoing revision and tighter accuracy requirements are expected. In this report, we compare the accuracy of four latest models of blood glucose monitoring systems using the current standard and tighter criteria.

Method – Accuracy of the four blood glucose monitoring systems for fingertip capillary blood testing was assessed at a diabetes clinic. A total of 80 diabetes subjects were included in the study. At the study centre, the trained operator tested the subject's fingertip blood in duplicate on the four systems and on a YSI glucose analyzer, which served as the reference. Accuracy was evaluated using ISO 15197:2003 and by calculating the percentage of meter results falling within ± 5%, ± 10% and ± 15% of the reference value for glucose concentrations 5.6 mmol/L (100 mg/dL) or higher and within ± 0.28, ± 0.56 and ± 0.83 mmol/L (± 5, ± 10 and ± 15 mg/dL) of the reference value for glucose concentrations below 5.6 mmol/L (100 mg/dL).

Results – Two out of the four blood glucose monitoring systems in this study met the minimum acceptable accuracy required by ISO 15197:2003. These were the FreeStyle Freedom Lite system and the OneTouch Vita system. When evaluated with tighter accuracy criteria, the FreeStyle Freedom Lite system had 99.4% of its results agreeing within ± 0.83 mmol/L (15mg/dL) or 15% of the reference and 92.5% of the results agreeing with ± 0.56 mmol/L (10 mg/dL) or 10% of the reference – a performance significantly ($p < 0.015$) better than that of the Accu-Chek Performa, OneTouch Ultra and OneTouch Vita systems. The FreeStyle Freedom Lite system had 55.6% of its results agreeing within ± 0.28 mmol/L (5 mg/dL) or 5% of the reference, significantly ($p < 0.006$) better than the Accu-Chek Performa and OneTouch Ultra systems.

Conclusions – Of the four latest models of blood glucose monitoring systems evaluated, the FreeStyle Freedom Lite system showed the highest level of accuracy. More accurate glucose results may help patients maintain their blood glucose levels with a higher degree of accuracy and the more accurate glucose monitoring systems are more likely to meet any new ISO standard and local regulatory requirements.

Self-monitoring of blood glucose with an accurate device is an integral component of effective diabetes management. ISO 15197,[1] the international standard that specifies accuracy requirements of blood-glucose monitoring systems for self-testing, was created in 2003. Some professional organizations and regulatory agencies are now proposing a tightening of the accuracy standard. Using ISO 15197:2003 and tighter criteria, we compared the accuracy of four latest models of blood glucose monitoring systems based on different measurement technologies.

MATERIALS AND METHODS

GLUCOSE MONITORING SYSTEMS

The technologies and features of the four systems evaluated in this study are shown in Table 1. Accu-Chek Performa and OneTouch Ultra meters require coding by the user, and they were properly coded by the trained operator at the study site before use. All systems and supplies were stored, handled and operated according to the manufacturer's instructions.

Table 1. Technologies and features of the four monitoring systems

	FreeStyle® Freedom Lite	**Accu-Chek® Performa**	**OneTouch® Ultra™**	**OneTouch® Vita™**
Manufacturer	Abbott Diabetes Care	Roche Diagnostics	LifeScan	LifeScan
Methodology	Coulometry, with the new FreeStyle Lite test strip with ZipWik™ tabs	Amperometry, with the new modified test strip (maltose interference free)	Amperometry	Amperometry
Enzyme	GDH-FAD	GDH-PQQ	GOx	GOx
Coding	No	Yes	Yes	No
Sample Size, μL	0.3	0.6	1.0	1.0
May apply second blood drop	Yes, within 60 sec	Yes, within 5 sec	No	No
Test Time, sec	As little as 4 sec	5	5	5
Referenced to plasma glucose values	Yes	Yes	Yes	Yes

REFERENCE GLUCOSE MEASUREMENT

The YSI 2300 STAT PLUS blood glucose analyzer (YSI Inc, Yellow Springs, OH) was used as the reference. The calibration accuracy of the YSI analyzer at the study site was validated by testing Randox glucose standards, which consist of six levels of glucose concentrations.

ACCURACY EVALUATION

The accuracy of the four monitoring systems for finger blood testing was evaluated at a diabetes clinic using one lot of test strips with the FreeStyle Freedom Lite and OneTouch Ultra systems and two lots of test strips with the OneTouch Vita and Accu-Chek Performa systems. The order of testing the four systems was randomized on each day of testing. A fingerstick was performed on each subject; the capillary blood from the fingertip was tested in duplicate on each system. Immediately after applying blood to the four systems, blood was collected from the same fingerstick into a heparin tube for testing in duplicate on the YSI analyser. The protocol specifies that the YSI test must be completed within 15 minutes of the first meter test and the duplicate YSI results must be within ± 0.2 mmol/L (± 4 mg/dL) of each other. The YSI whole blood glucose results were converted to plasma equivalent results and these results used to compare to the test strip results obtained with the four glucose monitoring systems. In

order to determine haematocrit levels, duplicate haemoglobin tests were performed on the HemoCue analyser with the whole blood sample collected for each subject.

RESULTS

A total of 80 diabetic subjects were enrolled at the study site. An ethics committee approved the study protocol and all subjects gave their informed consent before participation. There were no protocol deviations and no subjects were excluded from the study or data analysis.

Based on the YSI results, blood glucose concentrations of the 80 subjects ranged from 3.0 – 27.9 mmol/L (54 to 502 mg/dL), with a mean value of 10.8 mmol/L (194 mg/dL) and a median of 10.4 mmol (187 mg/dL). The haematocrit of the 80 subjects ranged from 36% to 55% (mean, 43.4% and median, 43%).

As shown in Table 2, two of the four systems met the minimum acceptable accuracy requirement of ISO 15197:2003[1] **–** At least 95 % of the individual glucose results shall fall within ± 0.83 mmol/L (15 mg/dL) of the results of the manufacturer's measurement procedure at glucose concentrations < 4.2 mmol/L (< 75 mg/dL) and within ± 20 % at glucose concentrations ≥ 4.2 mmol/L(≥ 75 mg/dL). However the OneTouch Ultra system fell just outside the criteria (94.4%).

When the accuracy criterion was tightened to ± 15% of the reference value, or ± 0.83 mmol/L (± 15 mg/dL) at glucose concentrations below 5.6 mmol/L (100 mg/dL), only the FreeStyle Freedom Lite system with 99.4% had ≥ 95% of the results within the tighter limits. The Accu-Chek Performa system had 85.5% of results within these limits while the OneTouch Ultra system had 84.4% of results and the OneTouch Vita had 93.8% of results within these limits.

Table 2. Percentage of meter results falling within various intervals of the reference glucose value

Accuracy Threshold	**5.55mmol/L (100mg/dL)**			**4.2mmol/L (75mg/dL)**
System	**% Within ± 0.28mmol/L (5mg/dL) or 5%**	**% Within ± 0.56mmol/L (10mg/dL) or 10%**	**% Within ± 0.83mmol/L (15mg/dL) or 15%**	**% Within ± 0.83mmol/L (15mg/dL) or 20%***
FreeStyle Freedom Lite	55.6	92.5	99.4	99.4
Accu-Chek Performa	39.0	69.2	85.5	93.7
OneTouch Ultra	39.4	67.5	84.4	94.4
OneTouch Vita	46.9	72.5	93.8	98.1

N = 159-160 tests on each glucose monitoring system.

*ISO 15197:2003 accuracy requirements: 95% of the individual glucose results shall fall within ± 0.83 mmol/L (15 mg/dL) of the results of the manufacturer's measurement procedure at glucose concentrations < 4.2 mmol/L (< 75mg/dL) and within ± 20 % at glucose concentrations ≥ 75mg/dL (≥ 4.2 mmol/L).

**Shaded areas indicate significant difference from the FreeStyle Freedom Lite system ($p < 0.015$).

When the accuracy criterion was tightened to ± 10% of the reference value or ± 0.56 mmol/L (± 10 mg/dL) at glucose concentrations below 5.6 mmol/L (100 mg/dL), the FreeStyle Freedom Lite system had 92.5% of results falling within the limits. The Accu-Chek Performa, OneTouch Ultra and OneTouch Vita had 69.2%, 67.5% and 72.5% of results respectively within these limits.

When the accuracy criterion was tightened to ± 5% of the reference value, or ± 0.28 mmol/L (± 5 mg/dL) at glucose concentrations below 5.6 mmol/L (100 mg/dL), 55.6% of FreeStyle Freedom Lite results,

39.0% of the Accu-Chek Performa results, 39.4% of the OneTouch Ultra results and 46.9% of the OneTouch Vita results fell within these very tight limits.

The FreeStyle Freedom Lite system had significantly ($p < 0.006$) more results falling within each set of limits in Table 2 than Accu-Chek Performa. The FreeStyle Freedom Lite system also had significantly more results falling within ± 0.83 mmol/L (15 mg/dl)/15% ($p < 0.015$) and ± 0.56 mmol/L (10 mg/dL)/10% ($p < 0.0001$) of the reference value, when the accuracy threshold was 5.6 mmol/L (100 mg/dL), than OneTouch Ultra and OneTouch Vita. At the very tight criteria of ± 0.28 mmol/L (± 5 mg/dL)/5%, OneTouch Vita was the only one system which did not have significantly different performance to the FreeStyle Freedom Lite system.

DISCUSSION

Self monitoring of blood glucose (SMBG) is an important component of the treatment plan of patients with diabetes. It enables patients achieve and maintain specific glycaemic goals.

According to ISO 15197:2003 the minimum acceptable accuracy for results produced by a blood glucose monitoring system is as follows: 95 % of the individual glucose results shall fall within ± 0.83 mmol/L (15 mg/dL) of the results of the manufacturer's measurement procedure at glucose concentrations < 4.2 mmol/L (< 75 mg/dL) and within ± 20 % at glucose concentrations ≥ 4.2 mmol/L (≥ 75 mg/dL). In this study, two of the four blood-glucose monitoring systems met the minimum acceptable accuracy required by ISO 15197:2003.

Although there are no outcome studies that substantiate improved patient benefits from greater accuracy of blood-glucose monitoring systems, it is logical to suggest patients would be able to maintain their blood glucose levels with a higher degree of accuracy if their meters were more accurate. Professional organizations such as the American Diabetes Association and the American Association of Clinical Endocrinologists and regulatory agencies such as the FDA in the US have indicated strong support for standards stricter than the ISO 15197:2003. The ISO Standard is now undergoing revision and tighter accuracy requirements are expected.

The 1986 consensus conference,[2] organized by the American Diabetes Association, led to the following recommendations: (1) With current systems, SMBG measurements should be within 15% of the results of the reference measurement; (2) The goal of all future SMBG systems should be to achieve variability (system plus user) of < 10% at glucose concentrations of 1.7 - 22.2 mmol/L (30 - 400 mg/dL) 100% of the time. In this study, the FreeStyle Freedom Lite system had 99.4% of its results agreeing within ± 15% of the reference, and 92.5% of the results agreeing with ± 10% of the reference. This performance is significantly better than that of the Accu-Chek Performa, OneTouch Ultra and OneTouch Vita systems.

In conclusion, of the four latest models of blood glucose monitoring systems evaluated, the FreeStyle Freedom Lite system showed the highest level of accuracy. More accurate glucose results may help patients maintain their blood glucose levels with a higher degree of accuracy, and the more accurate glucose monitoring systems are more likely to meet any new ISO Standard and local regulatory requirements.

REFERENCES

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