Ascensia BREEZE2 Glucose FreeStyle *Lite* Glucose

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Summary of two evaluations organised by SKUP Report SKUP/2007/59 and SKUP/2007/64

Background

In order to give reimbursement for glucose test strips in Norway, the Norwegian Labour and Welfare Organisation (NAV) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients. The results of the evaluation must fulfil the quality goals set in ISO 15197 (TE within ±20 %).

Ascensia BREEZE2 and FreeStyle *Lite* are meters designed for glucose self-measurements by diabetes patients. Ascensia BREEZE2 is produced by Bayer HealthCare and supplied in Scandinavia by Bayer. FreeStyle *Lite* is produced by Abbott Diabetes Care Inc. and supplied in Scandinavia by Abbott. Ascensia BREEZE2 and FreeStyle *Lite* were launched onto the Norwegian market in October 2007. The evaluation of Ascensia BREEZE2 was carried out during the autumn of 2006, and the evaluation of FreeStyle *Lite* during spring 2007.

The aim of the evaluations

The aim of the evaluations is to

- reflect the analytical quality under standardised and optimal conditions, performed by biomedical laboratory scientists in a hospital environment
- reflect the analytical quality achieved by the intended users (approximately 160 diabetes patients participated in the two evaluations)
- compare the analytical quality among trained and un-trained diabetes patients
- compare the analytical quality among diabetes patients before and after three weeks of practice
- check the variation between three lots of test strips
- examine if hematocrit interferes with the glucose measurements
- evaluate the user-friendliness of the device
- evaluate the user guide

Materials and methods

Approximately 80 diabetes patients took part in each evaluation. Half of the diabetes patients had two consultations (the "training group") and the rest of them had one consultation (the "mail group"). At the first consultation the diabetes patients in the "training group" were given a standardised instruction about the device before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice on the device. In addition, two capillary samples were taken for measurements with a designated comparison method. The diabetes patients in the "mail group" received the device by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they were called for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide.

Results, Ascensia BREEZE2

The precision of Ascensia BREEZE2 was good. The repeatability CV was approximately 3 % under stan-

dardised and optimal measuring conditions and between 3 and 5 % when the measurements were performed by the diabetes patients.

The agreement with a designated comparison method was good. The quality goal set in ISO 15197 was achieved under standardised and optimal measuring conditions. When handled by the diabetes patients, Ascensia BREEZE2 also showed accurate results. These results were within an "adjusted ISO-goal" (TE within ±25 %) and also within the quality goal set in ISO 15197 (Fig. 1).

The three lots of test strips used in this evaluation all gave glucose results in agreement with the comparison method. No significant difference was pointed out.

Glucose measurements on Ascensia BREEZE2 seemed to be affected by hematocrit. The range of hematocrit-values in the samples was 33 – 50 %.

The diabetes patients summarised the Ascensia BREEZE2 device as easy to use. Most of them were pleased with the device. The diabetes patients that had used the user guide were satisfied with the guide.

Results, FreeStyle *Lite*

The precision of FreeStyle *Lite* was good. The repeatability CV was between 2 and 3 % under standardised and optimal measuring conditions and approximately 4 % when the measurements were performed by the diabetes patients.

The agreement with a designated comparison method was good. The quality goals set in ISO 15197 was achieved under standardised and optimal measuring conditions. When handled by the diabetes patients, FreeStyle *Lite* also showed accurate results. These results were within the "adjusted ISO-goal" and also within the quality goal set in ISO 15197 (Fig. 2).

Two of the three lots of test strips used in this evaluation gave lower values than the comparison method. The third lot of test strips gave higher values than the comparison method. The deviations were small, but statistically significant.

Glucose measurements on FreeStyle *Lite* did not seem to be affected by hematocrit. The range of hematocrit-values in the samples was 31 – 48 %.

The diabetes patients summarised the FreeStyle *Lite* device as easy to use. Most of them were pleased with the device. Most of the diabetes patients that had used the user guide were satisfied with the guide.

Conclusion

The precision of Ascensia BREEZE2 and FreeStyle *Lite* was good. The accuracy was also good and the results were within the quality goal set in ISO 15197. Glucose measurements on Ascensia BREEZE2 seemed to be affected by hematocrit, while the glucose measurements on FreeStyle Lite did not seem to be affected by hematocrit. The users found the devices easy to use and were quite satisfied with the devices and the user guides.

The complete evaluation reports are available at www.skup.nu

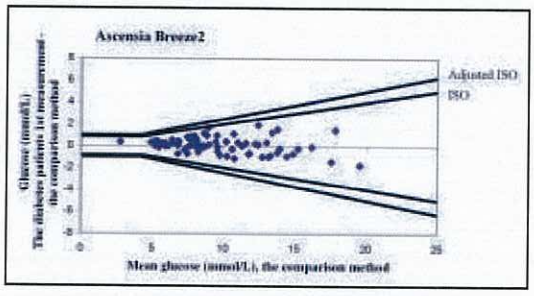

Figure 1. Accuracy. The diabetes patients' self-measurements at the final consultation. Three lots of test strips. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Ascensia BREEZE2 and the mean value of the duplicate results on the comparison method, n = 75.

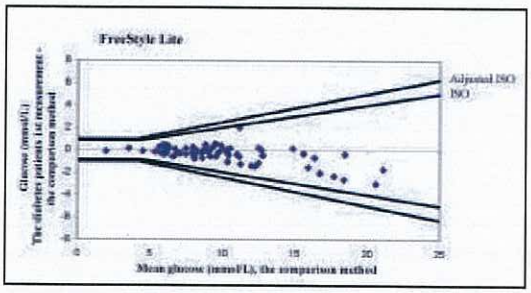

Figure 2. Accuracy. The diabetes patients' self-measurements at the final consultation. Three lots of test strips. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on FreeStyle Lite and the mean value of the duplicate results on the comparison method, n = 76.