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Evaluation of the FreeStyle Libre, a flash glucose monitoring system, in client-owned cats with diabetes mellitus

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Abstract

Objectives Home blood glucose monitoring using a portable blood glucose meter is important in the management of feline diabetes mellitus, but taking blood samples may be stressful for owners and cats. A flash glucose monitoring system measuring interstitial glucose, such as the FreeStyle Libre, overcomes some of these drawbacks. The aim of this study was to evaluate the practical use and analytical and clinical accuracy of the FreeStyle Libre in 41 client-owned diabetic cats.

Methods In this prospective study, interstitial glucose concentrations were measured with the FreeStyle Libre and compared with blood glucose concentrations measured with a portable blood glucose meter (AlphaTRAK) on days 1, 7 or 8 and 14 after application of the device. Cat behaviour during application, location, skin reaction at the attachment site and owner satisfaction were assessed. Accuracy was determined by fulfilment of ISO 15197:2013 criteria, including Bland–Altman plotting and error grid analysis.

Results Placing the device was easy, with 70% of cats showing no reaction. Most sensors were placed on the thoracic wall. Skin reactions at the attachment site were not present or mild in almost all cats. Owners were very satisfied with the use of the FreeStyle Libre. Median functional life of the sensor was 10 days (range 1–14). Good correlation was found between interstitial and blood glucose measurements (rho[ρ] = 0.88, $P < 0.0001$). Fifty-three percent of interstitial glucose concentrations were within a maximum deviation of 15% from blood glucose concentrations and 92.7% were within the safe risk zones 0 and 1 of the surveillance error grid.

Conclusions and relevance The flash glucose monitoring system was easy to use and owners of diabetic cats were satisfied with its use. Although the device did not completely fulfil ISO requirements, it is sufficiently accurate for glucose monitoring in diabetic cats.

Keywords: Non-invasive glucose measurement; sensor; interstitial glucose; accuracy; owner experience

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Introduction

Diabetes mellitus (DM) is one of the most common endocrine diseases in cats, with a reported prevalence of 1:100 to 1:500, depending on the studied population.[1–6] Treatment of DM consists of insulin injections, often combined with a high-protein, low-carbohydrate diet.[1,2,6,7] Successful management of feline DM comprises maintenance of a stable body weight, minimal or no clinical signs, owner perception of a good quality of life, avoidance of complications of DM, such as diabetic ketoacidosis and peripheral neuropathy, and avoidance of hypoglycaemia.[1,2,6,8]

Achieving diabetic remission is also a reasonable goal in diabetic cats. One of the predictors of diabetic remission is achieving excellent glycaemic control within 6 months of diagnosis, probably because early effective glycaemic control can resolve glucotoxicity before there

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is permanent loss of sufficient beta (β) cells to maintain euglycaemia.[2,6,8–12] Traditional methodologies to obtain information regarding glycaemic control include spot blood glucose (BG) measurement, urine glucose measurement, measurement of serum fructosamine concentration, in-hospital BG curves (BGCs) and at-home BGCs.[13] All these methods can be challenging for both owner and the veterinary healthcare team and have their limitations in adequately monitoring the DM therapy.[1,2,6,8,13,14]

BGCs are not only helpful in evaluating the DM therapy, but can also be used to identify clinically undetectable hypoglycaemia, and to determine preinsulin BG, BG nadir, duration of insulin effect, degree of BG fluctuation and the presence of the Somogyi phenomenon.[1,2,15,16] Measurement of BG with portable BG meters (PBGMs) are precise enough when compared with results acquired from automated chemistry analysers, although some PBGMs are more accurate than others.[2,8,14,15,16] At-home BG monitoring using PBGMs can be adopted successfully by most owners of diabetic cats;[1,12,14,15,17,18] however, not all owners are able to obtain an at-home BGCs.[2,14,15] Moreover, BGCs can vary from day to day, even when performed at home.[2,8,15,19]

To assess glucose concentrations more frequently and without the need to sample capillary blood, continuous glucose monitoring systems (CGMSs) have been developed for diabetic humans. The CGMS measures the concentration of interstitial glucose (IG) every few minutes to supply almost continuous information on glucose concentrations. It has been demonstrated that the glucose concentration in the subcutaneous interstitial fluid correlates well with the glucose concentration in whole blood.[7,20–23] In humans, the average delay between a change in the glucose concentration in blood vs interstitial fluid is about 5 mins, making the CGMS reliable for real-time monitoring.[21,23] Multiple CGMSs, such as the MiniMed Gold (Medtronic), GlucoDay (Menarini Diagnostics), Guardian Real-Time (Medtronic) and iPro (Medtronic) have been reported for use in cats and dogs.[6,24–32] The FreeStyle Libre (Abbott Laboratories) is a relatively new flash glucose monitoring system (FGMS) licensed for use in people (CE mark, August 2014). The FreeStyle Libre measures IG every minute, is calibrated in the factory and does not need additional BG measurements to calibrate at home. The sensor is suitable for up to 14 days of use.[6,20,22,33–35] To date, only a few studies have been published regarding the use of the FreeStyle Libre in dogs and cats,[13,33–41] with only four of them specifically in cats.[13,35,37,40]

The aim of this study was not only to add further case numbers on analytical and clinical accuracy of the FreeStyle Libre to the previous studies, but also to evaluate the practical use of the device, including user convenience for the owner, in client-owned cats with DM.

Materials and methods

Study design

The study was performed in client-owned diabetic cats with an indication for continuous glucose monitoring at the AniCura Veterinary Referral Centres at Dordrecht and Haaglanden. At first presentation, breed, age, sex, body weight, body condition score (BCS) and medical history were documented. Furthermore, a physical examination was performed to determine whether there were any contraindications to study entry.

During application of the FreeStyle Libre, the behaviour of the cat was assessed (score 0–5, with 0 indicating no reaction during placement and 5 indicating a very severe reaction during placement). On the first day, 4–5 capillary BG measurements from the lateral ear margin of the right or left ear were performed by an experienced veterinary nurse with intervals of at least 30 mins. At the time of capillary BG measurement, the sensor was read out by the same person. Both glucose results were noted. This procedure was repeated on day 7 or 8 (T2, day 7 or 8) and on day 14 (T3) if the sensor was still working at this point in time. All measurements of capillary BG took place in the veterinary clinic.

Immediately after removal or loss of the sensor, the skin in the area where the sensor had been attached was examined. If the sensor was removed at home, owners were asked to photograph the skin at the sensor area. Reactions were graded subjectively by the author, as shown in Table 1.

After finishing the study, owners were asked to complete a questionnaire regarding the use of the device, with questions on how long the sensor had worked, why the sensor stopped working, ease of use, if the cat seemed bothered by the device, overall rating of the device and whether the owner would use it again and recommend it to other owners of diabetic cats.

The study design did not require approval by an ethics committee. Cat owners' consent was obtained prior to the start of the study.

Table 1 Grading system of skin reactions at the sensor area after removal of the sensor

Description	Grade
No irritation of the skin, possibly some tissue adhesive remnants	1
Light pink skin, impression of sensor visible, no swelling, no painfulness	2
Some erythema, some swelling, no painfulness	3
Clear erythema, swelling, painfulness, no discharge	4
Clear erythema, swelling, painfulness, discharge present	5

Animals

The study included 41 diabetic cats; 35 domestic shorthairs, two Maine Coons, one Abyssinian, one British Shorthair, one Norwegian Forest Cat and one Sphynx cat. All cats were neutered. There were significantly ($P = 0.001$) more male cats (n = 31) than female cats (n = 10). The median age of the cats was 11.4 years (range 4.7–17.1) and the median body weight was 5.2 kg (range 3.7–7.2). The median BCS was 6/9 (range 3–9). Eighteen cats were treated with protamine zinc recombinant human insulin (ProZinc; Boehringer Ingelheim), 18 cats with porcine insulin zinc suspension (Caninsulin; MSD Animal Health) and five with glargine (Lantus; Sanofi).

FGMS and PBGM device

All the FreeStyle Libre sensors were placed by the first author (MK), either on the dorsolateral thoracic wall or between the shoulders on the dorsum (Figure 1).[42] In all but one cat, sedation was not necessary. Sedation was given using butorphanol (0.4 mg/kg IM [Dolorex; MSD Animal Health]).

The readings of the FreeStyle Libre were compared with capillary BG concentrations as a reference. The PBGM AlphaTRAK (Zoetis), validated for use in cats, was used to determine capillary BG concentrations. The working range of the AlphaTRAK is 1.1–41.7 mmol/l; that of the FreeStyle Libre is 1.1–27.8 mmol/l.[43] All concentrations above and below the detection limit of the sensors were excluded. Based on capillary BG measurements, samples were classified as hypoglycaemic (<3.9 mmol/l), normoglycaemic (3.9–10.0 mmol/l) or hyperglycaemic (>10.0 mmol/l).[41]

Statistical analysis

Statistical analysis was performed using IBM Statistics SPSS 26. Normality was assessed with the Shapiro–Wilk test and non-parametric tests were used accordingly. The Mann–Whitney U-test was used to compare differences in the reactions of the cats, sensor location and length of sensor function time. Correlation between the IG measured by the FreeStyle Libre and BG measured with the PBGM was evaluated using Pearson's correlation. Statistical significance was set at $P \leqslant 0.05$.

Accuracy of the FreeStyle Libre

Analytical accuracy was calculated by plotting the differences between paired IG and BG against the PBGM results in modified Bland–Altman plots using MedCalc for Windows software, version 20.015.

Clinical accuracy of the FreeStyle Libre was evaluated by analysing the consensus error grid using the PBGMs Surveillance Program (SEG Software; diabetestechnology.org).[44,45] A scatter plot was made of the estimated BG concentrations (here: IG measurements obtained by the

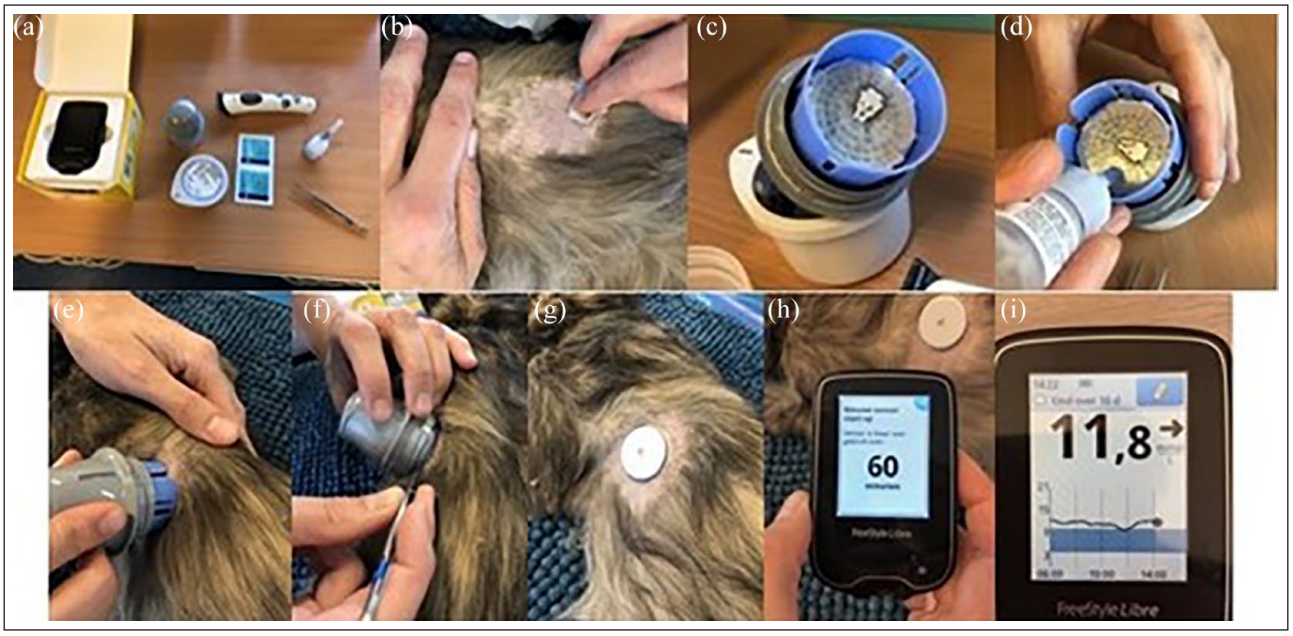

Figure 1 FreeStyle Libre application. (a) The flash glucose monitoring system was placed using the device that is supplied by the manufacturer and as per the manufacturer's instructions. (b) The site of application was clipped and cleaned with the supplied disinfecting tissues. (c–e) Four to six drops of cyanoacrylate tissue adhesive (3M Vetbond) were placed on the contact surface of the sensor prior to placement. (f,g) To facilitate sensor installation unit removal, forceps were used for fixation of the sensor unit at the adhesive edge. (h) Following placement, the device was scanned immediately to link it to the reader. (i) A 1 h automatic calibration period is required before data collection can be started

FreeStyle Libre, *y*-axis) vs measured BG obtained by the PBGM (*x*-axis) on a surveillance error grid (SEG) (see the supplementary material).

The FreeStyle Libre was further evaluated according to its clinical accuracy following ISO 15197:2013 criteria,[46] which determine the minimum performance standards for PBGMs in humans (see the supplementary material).

Results

Placement and use of sensor

In 32 cats the sensor was attached on the right dorsolateral thoracic wall; in nine cats it was attached on the dorsal aspect of the neck. In most cats (29/41; neck region 6/9, thoracic wall 23/32) there was no noticeable reaction to the placement of the sensor. Seven of 41 cats (neck region 2/9, thoracic wall 5/32) had a very small reaction (turning one ear backwards or ducking) and 3/41 cats (neck region 1/9, thoracic wall 2/32) showed a defensive reaction (flattening ears, rippling of skin or hissing). In two cats, the reaction was not recorded. There was no significant difference in the reaction of the cats between the sensor being placed on the thorax or neck ($P = 0.67$). Subjectively, the sensors were easier to place on the dorsolateral thoracic wall vs the dorsal aspect of the neck. Extra glue was needed to fix the sensor after being placed on the dorsal aspect of the neck in 4/9 cases; this was never necessary when it was placed on the thoracic wall ($P < 0.0001$).

The median functional use of the sensor was 10 days (range 1–14 days). Ten sensors reached a measurement period of 14 days (neck region 1/9, thoracic wall 9/32). Reasons that the remainder of the sensors did not reach this period were sensor malfunction (16/31: neck region 3/8, thoracic wall 13/23), removal of the sensor by the cat (6/31: neck region 3/8, thoracic wall 3/23) or spontaneous loss of the sensor (8/31: neck region 2/8, thoracic wall 6/23). In one cat the reason was unknown. There were three cats in which the sensor worked for 24 h or less (one neck region, two thoracic wall); one of these cats removed the sensor directly after it arrived at home, one lost the sensor after getting into a fight with the other cat at home and in one cat there was a sensor malfunction. There was no statistically significant difference ($P = 0.083$) between the mean length of measurement period of the sensor when it was placed on the dorsal neck (mean 6.6 days; range 1–14) or thoracic wall (mean 9.6 days; range 1–14).

Owners were asked whether they had the impression their cat was bothered by the sensor. Answers could vary from 0 (absolutely not bothered) to 10 (bothered a lot). Thirty-eight owners answered the question; the median value was 1.5 (range 0–8). If the owners answered that their cat was bothered by the sensor, they were asked what they noticed in their cat. Twenty owners answered this question; 13 owners (neck region 5/9, thoracic wall 8/11) answered that the cat was licking or scratching at the sensor site, five owners (neck region 3/9, thoracic wall 2/11) stated that their cat was actively trying to remove the sensor and two owners noticed different, unspecified behaviour in the cat (neck region 1/9, thoracic wall 1/11). There was no significant correlation between the function time of the sensor and the degree to which the cat was bothered by the sensor, according to the owner ($P = 0.45$). Cats from which the sensor came off (either spontaneously or removed by the cat) were not judged to be more bothered by the sensor than cats from which the sensors did not come off ($P = 0.11$).

In 33 cats, the skin reaction after removal of the sensor was graded. No irritation of the skin was found in 17 cats, light pink skin was found in 14 cats, in one cat there was some erythema and in one cat there was erythema and painfulness. The sensors were attached with the same amount of glue in all cats, except four (neck region 4/9, thoracic region 0/32) where 1–2 extra drops of glue were used. In these four cats, two showed no irritation of the skin, one cat showed light pink skin and in one cat the reaction of the skin was not recorded. No correlation was found between the amount of skin reaction and the length of sensor placement.

Owners rated the user-friendliness of the FreeStyle Libre on a scale of 0 (very difficult to use) to 10 (very user friendly) and the overall use of the device on a scale of 0 (very bad idea) to 10 (great idea). Thirty-eight owners answered the question. User friendliness scored an average of 9.2 (range 6–10), and overall satisfaction scored an average of 9.1 (range 6–10). Reasons for these high scores were that it was felt that the FreeStyle Libre was less stressful for the cat (and the owner) than capillary BG measurement. The owners also liked the continuous monitoring and the insight it gave them on the glucose values of their cat. Drawbacks mentioned were price, sensor malfunctions, size of the sensor and operating time. The overall satisfaction of owners with the use of the FreeStyle Libre was not correlated to the time that the sensor stayed on.

The owners of 30 cats would use the FreeStyle Libre again, five owners would not, one was unsure and for five cases it was unknown. The owners of 31 cats would recommend the FreeStyle Libre to other owners of diabetic cats, four owners would not, one was unsure and in five cases it was unknown. Owners stated various reasons to use the FreeStyle Libre again. The most common reason was 'very useful in helping to regulate and monitor the cat's diabetes because it's possible to determine nadir and effect of insulin'. Although, on average, the satisfaction of the owner was not related to the length of the sensor function, for three owners a reason they would not use the FreeStyle Libre again was that it did not work long enough and/or was too expensive.

Analytical accuracy

A total of 278 data pairs of glucose measurements were assessed. Median glucose concentration in all measured

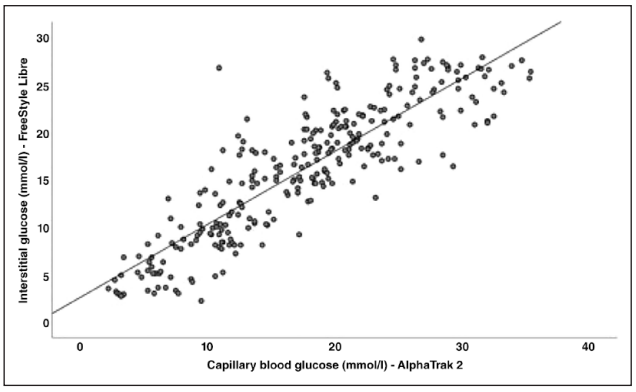

Figure 2 Relationship between blood glucose concentrations measured with a portable blood glucose meter (AlphaTrak2) and interstitial glucose concentrations measured with the FreeStyle Libre. Results of linear regression and Spearman's rank correlation analysis (rho = 0.88, $P < 0.0001$)

samples was 18.1 mmol/l (range 2.2–35.4) using the PBGM and 17.1 mmol/l (range 2.2–27.8) using the FreeStyle Libre. A significant ($P < 0.0001$) positive correlation ($\rho = 0.88$) was found between IG measured by the FreeStyle Libre and the BG measured by the PBGM (Figure 2).

Based on the reference method (capillary BG concentrations), 3% (n = 9/278) of the samples were in the hypoglycaemic range (<3.9 mmol/l), with a median glucose concentration of 3.1 mmol/l (range 2.2–3.4). Fifteen percent (n = 41/278) of the samples were in the normoglycaemic range (3.9–10 mmol/l), with a median glucose concentration of 7.1 mmol/l (range 4.5–9.8). Eighty-two percent (n = 228/278) of the samples were in the hyperglycaemic range (>10 mmol/l), with a median value of 18.3 mmol/l (range 10.2–35.4).

It was not possible to perform 4–5 measurements at each time point in all cats. Sometimes only two measurements could be performed in a cat at a certain time. In the end, paired samples were collected at the following times after sensor placement: T1 – 171 samples (61%); T2 – 88 samples (32%); T3 – 19 samples (7%). Statistically significant ($P = 0.0001$) positive correlations were found at each of the three time points with Spearman's rank correlation coefficients (ρ) of 0.86, 0.86 and 0.90, respectively.

Separation of the data pairs in glucose measurements from sensors placed on the thorax (n = 230) and placed on the neck (n = 48) revealed significant ($P < 0.0001$) correlation, with a ρ of 0.91 and 0.63, respectively. These correlation coefficients differed significantly (observed z value of 0.17, which is <1.645 [critical value at a significance level of $P < 0.05$]).[47]

Using the PBGM as a reference, the FreeStyle Libre underestimated BG readings in 184 (66.2%) of the samples, overestimated them in 90 (32.4%) and they were identical in four samples (1.4%).

Clinical accuracy according to ISO 15197:2013 criteria and consensus error grid

With regard to the ISO 15197:2013 criteria, 52.9% (n = 147/278) of the IG results were within the range of reference measurements ± 15% (or ± 0.83 mmol/l for BG concentrations <5.5 mmol/l) (Figure 3).

By analysing the SEG, using the PBGM as a reference, 78.5% of the glucose values fell in the SEG risk level 0 and 14.2% fell in the SEG risk level 1, totalling 92.7% (n = 254/278) of the samples. Only 4.7% of glucose values fell in the SEG risk level 2, 2.2% fell in risk level 3 and one pair fell in the SEG level 4 (Figure 4 and Table 2).

Discussion

The application of the FreeStyle Libre sensor was easy and painless in most cats, and only a few cats showed a slight reaction. The sensors were all placed by the same person (MK) and were easier to place on the dorsolateral thoracic wall than the dorsal aspect of the neck. This subjective observation is underlined by the fact that in nearly half of the cats where the sensor was placed on the neck, extra glue was necessary to fix the sensor to the skin. Moreover, the correlation between BG and IG was higher if the sensors were placed on the thorax than on the neck. In a study by Hafner et al,[42] a Guardian Real-Time sensor placed in the dorsal neck region had a higher proportion of successful first calibrations and appeared to be clinically more accurate and reliable than those that were placed in the lateral chest wall or knee fold. However, the Guardian Real-Time is a different type of sensor and the

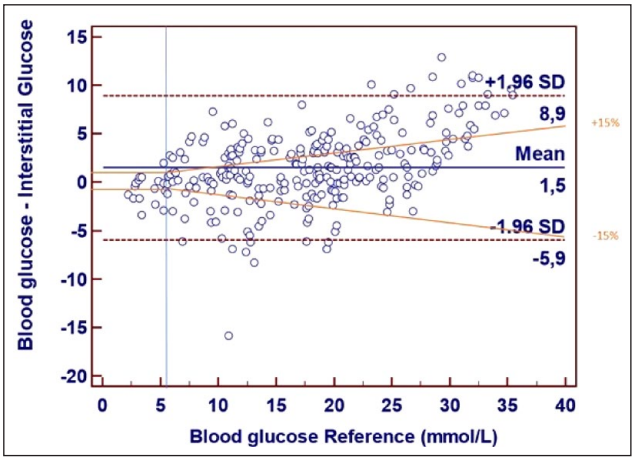

Figure 3 Bland–Altman plot representing the differences between the glucose concentrations obtained using the FreeStyle Libre vs those obtained using the PBGM (reference). On the x axis the reference glucose values are plotted against the absolute errors for each corresponding value. The standard required limits are defined by the orange symmetric lines: at ± 0.83 mmol/l from the reference value for glucose concentrations <5.5 mmol/l and ± 15% from the reference values for glucose concentrations >5.5 mmol/l

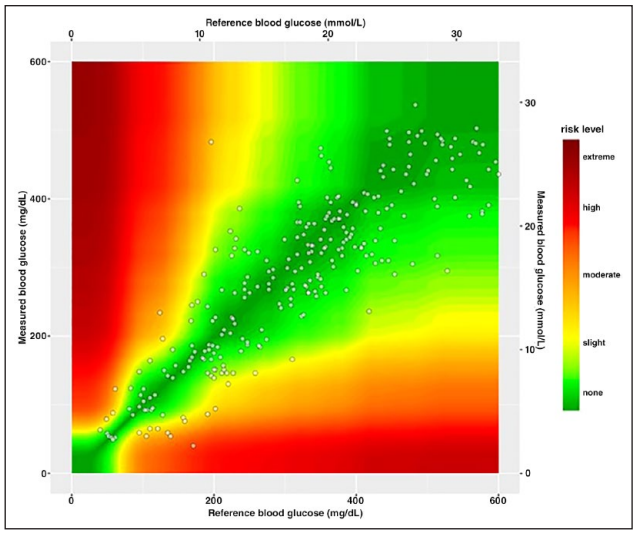

Figure 4 Surveillance error grid analysis representation. The reference blood glucose concentrations (obtained by the portable blood glucose meter) are on the *x* axis and plotted against the interstitial glucose measurement (obtained by the FreeStyle Libre) on the *y* axis. The different zones designate the magnitude of risk, reading from green (no risk) to dark red (extreme risk).[42,43,46,47] See also Table 2

Table 2 Surveillance error grid (SEG) analysis: results from Figure 4 plotted, with risks segmented into eight zones of severity

SEG risk level	SEG risk category	Number of pairs	Percentage
0	None	215	78.5
1	Slight, lower	39	14.2
2	Slight, higher	13	4.7
3	Moderate, lower	6	2.2
4	Moderate, higher	1	0.4
5	Severe, lower	0	0
6	Severe, upper	0	0
7	Extreme	0	0

numbers in that study were small. In contrast, a study by Shoelson et al[13] showed a higher complication rate (early detachment, mild or major dermatological changes or a dysfunctional sensor) in cats where the FGMS was applied on the dorsal neck (n = 2/3) than cats in which the FGMS was applied on the dorsolateral aspect of the thorax (n = 8/30).

The FreeStyle Libre sensor is designed to be worn for a 14-day period. In the present cohort of diabetic cats, 24% completed the 14-day period, which is very similar to the results of Deiting and Mischke,[35] where 20% (n = 9/46) of the sensors were worn for a period of 14 days, and much longer than the cats in the study of Del Baldo et al,[37] where only 1/20 sensors was still attached and working for 14 days. In contrast, in the study by Shoelson et al,[13] 61% (n = 20/33) of the sensors worked for 14 days. The reason for this difference is speculative, but, in the latter study, sensors were sometimes placed more than once on a cat. It is possible that cats get used to wearing the sensor and are therefore less likely to try and remove them. Interestingly, a study in diabetic children and adolescents[48] found an early detachment rate of the sensor of 28.4%, which is comparable to the rate of 26% of spontaneous loss of the sensor in the present study.

Although the majority of sensors did not work for the full 14 days, the owners of the cats were, overall, very satisfied with the FGMS, with a score of 9.1/10. Almost three-quarters of the owners would use the FreeStyle Libre again and recommend its use to other diabetic cat owners.

Most cats had no clinically detectable skin reactions and 42% had a mild skin reaction after removal of the sensor; only two cats had major dermatological changes (swelling, clear erythema and/or painfulness). Cyanoacrylate tissue glue is considered to be safe and effective for superficial skin closure in cats,[49] but both the sensor's built-in adhesive (isobornyl acrylate and *N*,*N*-dimethylacrylamide) and cyanoacrylate are known to cause allergic contact dermatitis in some people. Studies have shown that up to 35% of people report dermatological problems when using a continuous glucose monitoring system.[44,50–53] It is unknown whether the cats in our study had skin reactions because of the sensor's adhesive, the cyanoacrylate glue or a combination thereof. In a study by Deiting and Mischke,[35] 36% of cats (n = 21/59) showed mild erythema and 3% (n = 2/59) showed a superficial dermatitis; however, in their study, sensors were attached with stitches rather than tissue adhesive. As the use of cyanoacrylate does not seem to result in a higher percentage of skin reactions, additional fixation of the sensor is advised in several studies. The results between fixation of the sensor with sutures vs tissue glue are similar, and the use of sutures might result in a higher percentage of cats reacting to the placement of the sensor. Our recommendation would be to use cyanoacrylate to fix the sensors onto the skin.[35,37]

We found a very strong positive correlation between IG and BG in the diabetic cats, similar to other studies in dogs and cats.[33–37] The correlation was better if the sensor was located on the thorax ($\rho = 0.91$) vs the dorsal neck ($\rho = 0.63$). This difference has not been described previously. In contrast, in the study of Del Baldo et al,[37] all sensors were placed on the dorsal neck and a correlation of 0.90 was found.

Analytical accuracy was determined using a modified Bland–Altman plot. In the present study, 52.9% of the glucose concentrations determined by the FreeStyle Libre were within the range of reference measurements ± 15% (or ± 0.83 mmol/l for values <5.5 mmol/l). This is comparable to results in earlier studies,[35,37] but significantly less than the 95% stated by the ISO 15197:2013 criteria. It

is, however, important to realise that the ISO 15197:2013 criteria are designed for human medicine, comparing PBGMs with the results of a standard reference method, both of which measure glucose in blood. Using the ISO 15197:2013 criteria while comparing two different compartments (blood and interstitial fluid) may be inappropriate because of physiological differences between these compartments. Therefore, the discrepancy between values measured with both methods may not be directly caused by a real inaccuracy of the FreeStyle Libre. Part of the discrepancy could be caused by the time lag for equilibration between the blood and interstitial space. Several studies have looked at this time lag and found values of 11.4–30 mins.[23,37] Stress hyperglycaemia is a well-recognised phenomenon in cats and changes in BG after stress can occur within a few minutes of stress induction.[54,55] Therefore, it is possible that getting the cat out of the cage to measure BG-induced stress causes the capillary glucose concentration to increase, whereas the glucose concentration in the interstitium was still in the equilibrium phase. This could tie in with the fact that the FreeStyle Libre underestimated BG values in more than 66% of the cases.

Clinical accuracy was determined by plotting data in a surveillance error grid. In our study, the FreeStyle Libre did not fulfil the human medicine requirements for PBGMs (ISO 15197:2013), because less than 97% (92.7%) of the results were in the risk levels 0 and 1. This percentage is lower than that reported by Deiting and Mischke (99.4%),[35] Del Baldo et al (100%)[37] and Corradini et al (98.7%).[33] However, results of the error grid analysis strongly indicate that the difference from reference measurements were only rarely clinically relevant, as 6.9% (n = 19/278) of the measurements were in the SEG risk levels 2 and 3 and only one measurement was in the SEG risk level 4 (ie, high moderate risk).

There were several limitations in this study. There was a reduced number of paired samples than anticipated because the sensor did not work for the entire 14 days in a significant number of cats. In future studies it might be better to accumulate more samples in the first 9–10 days after placing the sensor. There were a limited number of data points in the hypoglycaemic and normoglycaemic range, which makes it difficult to investigate the accuracy in these ranges. Larger studies will be necessary to evaluate whether there are statistical differences between sensors placed either on the neck or on the thoracic wall.

Conclusions

Although the ISO 15197:2013 requirements were not completely fulfilled, the FreeStyle Libre provides sufficiently clinically accurate estimates of BG concentrations. As the sensor is also easy and almost painless to place, is well tolerated, has good skin compatibility and is user friendly, the FreeStyle Libre is a useful device with which to evaluate glycaemic control in diabetic cats.

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Supplementary material The following file is available online:
File 1: Determination of clinical accuracy of FreeStyle Libre.

Conflict of interest The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical approval The work described in this manuscript involved the use of non-experimental (owned or unowned) animals. Established internationally recognised high standards ('best practice') of veterinary clinical care for the individual patient were always followed and/or this work involved the use of cadavers. Ethical approval from a committee was therefore not specifically required for publication in *JFMS*. Although not required, where ethical approval was still obtained, it is stated in the manuscript.

Informed consent Informed consent (verbal or written) was obtained from the owner or legal custodian of all animal(s) described in this work (experimental or non-experimental animals, including cadavers) for all procedure(s) undertaken (prospective or retrospective studies). For any animals or people individually identifiable within this publication, informed consent (either verbal or written) for their use in the publication was obtained from the people involved.

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