Received: 29 January 2020 | Accepted: 22 February 2020

DOI: 10.1002/edm2.125

ORIGINAL RESEARCH ARTICLE

Endocrinology, Diabetes & Metabolism Open Access WILEY

Effects of unrestricted access to flash glucose monitoring in type 1 diabetes

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Abstract

Aims: We assessed adherence and long-term effects on HbA1c of unrestricted access to flash glucose monitoring (FGM) in a single diabetes centre.

Methods: In this observational study, we reviewed data files for all 411 patients with type 1 diabetes attending our clinic during a 2-year period. Adherence was reported in those who initiated FGM in our clinic (n = 321). Baseline and final HbA1c were noted for patients who continued FGM for more than 6 months without clinical conditions or interventions at baseline that could interfere with the effect of FGM on glycaemic control (n = 270).

Results: After 2 years, the fraction of patients using FGM increased from 3% to 72%. Adherence to FGM was 88%. Baseline and final HbA1c was median (interquartile range) 63 mmol/mol (56, 74) (7.9% (7.3, 8.9)) and 59 mmol/mol (53, 68) (7.6% (7.0, 8.4)), respectively. The estimated difference final-baseline HbA1c was −4 mmol/mol (95% CI −5, −3) (−0.4% (−0.5, −0.3)) ($P < .001$). No significant difference was seen for patients with baseline HbA1c ≤ 7% (53 mmol/mol). The interval from initiation of FGM to final HbA1c was median 562 days (IQR 417, 662). The number of scans/day was median 11 (IQR 8, 13) and correlated negatively with both final and baseline HbA1c but not with change in HbA1c.

Conclusions: Following the introduction of unlimited access, nearly three quarters of the patients were FGM users. Long-term adherence was good, and HbA1c improved in all patients except in those with optimal glycaemic control at baseline.

KEYWORDS

flash glucose monitoring, intermittently scanned continuous glucose monitoring, type 1 diabetes

1 | INTRODUCTION

Flash glucose monitoring (FGM) enables patients to have information about their interstitial glucose concentration by sweeping a reading unit or a smartphone close to the sensor needle placed on the upper arm. This gives information about the actual glucose level; tendency arrows indicate if the value is stable, rising or falling; and a curve with information about glucose level for every 15 minutes shows trends the preceding 8 hours. The sensor needs no calibration, and it must be replaced after 14 days.

One randomized study including adult patients with HbA1c ≤ 58 mmol/mol (7.5%) reports reduced time in the hypoglycaemic range after 6 months for all patients using FGM[1] and for the subgroup with multiple daily injection (MDI) therapy[2] compared with self-monitored glucose test of capillary blood glucose. Despite widespread use of FGM in type 1 diabetes,[3] no randomized study has described the long-term effect on HbA1c in an unselected population. A recent study from two hospitals in Scotland reports a 4 mmol/mol reduction in HbA1c in the first patients started on FGM funded by the National Health Service (NHS).[4]

FGM was introduced in Denmark in 2016, initially with unclear funding and with no possibility for patients to purchase the system in Denmark. In 2019, the five Danish regions, which are the administrative units and formal owners of Danish public hospitals, decided that with a few exceptions, FGM in adult type 1 diabetic patients should offered only to those with HbA1c > 70 mmol/mol (8.6%).

In this observational study, we report the 'real world' long-term efficacy and adherence to FGM in a single Danish diabetes centre, which until 1 July 2019 had the opportunity to offer unrestricted access to FGM to individuals with type 1 diabetes.

Novelty statement

What is already known?

- Flash glucose monitoring in type 1 diabetes improves HbA1c in observational studies with duration of <1 year.

What this study found?

- Baseline HbA1c was reduced with a follow-up period of ~1½ year. After 2 years of unlimited access to flash glucose monitoring in a single diabetes centre, the fraction of users increased from 3% to 72%, indicating a high degree of patient satisfaction.

What are the clinical implications to this study?

- The beneficial effect of flash glucose monitoring persisted during long-term follow-up. There is no clinical argument to restrict reimbursement of flash glucose monitoring.

2 | METHODS

The study population comprised all individuals with type 1 diabetes (n = 411) attending the diabetes clinic in Regional Hospital Silkeborg in the 2-year period from 1 July 2017 to 1 July 2019.

During this period, the Freestyle Libre flash glucose monitor (Abbott, Witney, UK) was introduced to patients visiting the outpatient clinic. For patients who were interested, the equipment was started either on the same day after a short (~20 minutes) individual training or a few weeks later in group sessions. Attending other diabetes management courses was not a prerequisite for starting FGM. We asked patients to make at least 10 daily scans. At the subsequent visits to the outpatient clinic, FGM data were downloaded from the Glooko + Diasend platform for inspection of the ambulatory glucose profile. This, in turn, served as background for discussion with patients about possibilities and limitations for optimizing their metabolic status.

For follow-up, each patient's electronic data file was reviewed, and we recorded any information about method for glucose monitoring, insulin delivery and clinical conditions that could affect glycaemic control. We noted the date when FGM was initiated and if relevant the date and reason for terminating FGM. The date and the value of the last HbA1c value before FGM and the final HbA1c value were also noted. Information about the number of scans for the past 90 days was available for a subgroup of patients in 2019.

The change in HbA1c was calculated for all patients who had been used the FGM for more than 6 months, except for patients with the following conditions at baseline: FGM initiated at another hospital, malignant diseases, invalid HbA1c, changing from multiple daily injections (MDI) to continuous subcutaneous insulin infusion (CSII) within the first 6 months after commencing FGM, type 1 diabetes diagnosed <6 months before commencing FGM, pregnant or lactating or on systemic steroid treatment.

The final HbA1c value was the last available value before 15 October 2019 or the last value after more than 6 months with FGM before death (from nonmalignant disease), moving to another hospital, initiating treatment with sodium-glucose cotransporter 2 inhibitors or glucagon-like peptide 1 analogues, changing from MDI to CSII or terminating FGM. For patients who were not exposed to FGM, the first HbA1c value after 1 July 2017 and the last value before 15 October 2019 were recorded.

HbA1c was measured with high-pressure liquid chromatography (HPLC) typically one week before the visit to the clinic. Tosoh HLC-723G8 was used until 1 June 2018 and Tosoh HLC-723G11 (Tosoh Europe, Tessenderlo, Belgium) for the remaining period. For a minority of patients, HbA1c was measured with point-of-care testing (POCT) using the DCA Vantage Analyzer (Siemens Healthcare GmbH, Erlangen, Germany) in the clinic on the day of their visit. The recorded baseline value and the final HbA1c value were HPLC values unless the baseline value was obtained more than 3 months before commencing FGM. In these cases, POCT values were used if available for both baseline and final values.

Collection of clinical data was approved by the local institution. No ethical approval was needed for this observational study.

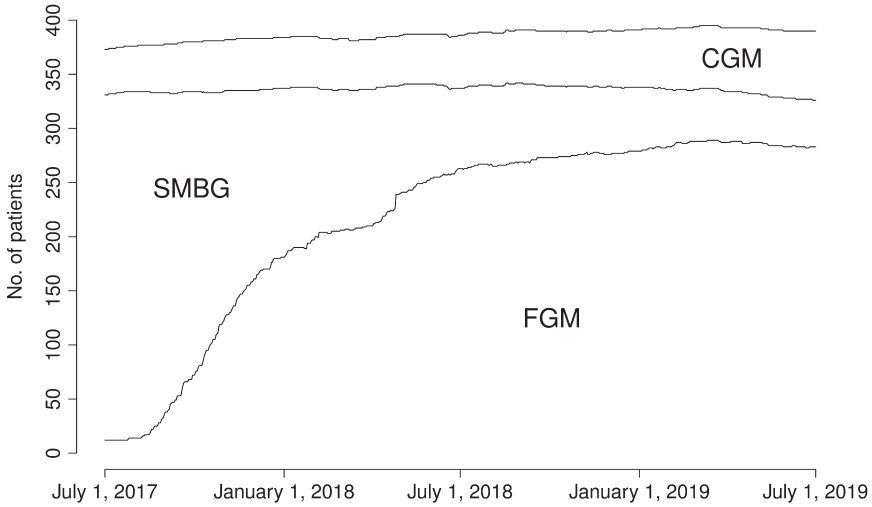

FIGURE 1 A stacked diagram illustrating the dynamics of the number of patients using FGM, SMBG and CGM for glucose monitoring during a 2-year period with free access to FGM

TABLE 1 Clinical characteristics of patients who initiated FGM in our clinic and those who did not. Age and diabetes duration is median (IQR) given per 1 July 2018

	Initiated FGM in our clinic (n = 321)	Did not initiate FGM (n = 85)	*P*
Sex (male/female)	183/138 (57%/43%)	48/37 (56%/44%)	NS
Age (years)	49.7 (35.9, 60.6)	46.3 (38.4, 61.2)	NS
Diabetes duration (years)	21.0 (11.0, 33.5)	25.0 (12.4, 38.3)	.037
MDI/CSII (Initial status)	261/60 (81%/19%)	43/42 (51%/49%)	<.001

2.1 | Statistical analysis

Truncated HbA1c values are not normally distributed, and for HbA1c and other continuous variables, data are presented as median and interquartile range (IQR). Paired observations were analysed with Wilcoxon signed rank test, and estimated differences were calculated as Hodges-Lehman median difference and 95% CI. Nonpaired data were compared with Mann-Whitney U test. Chi-square test was used for discrete variables. A Kaplan-Meir analysis was applied for reporting adherence to FGM. Bivariate correlations were assessed with calculation of Spearman's rho. Statistical significance was $P < .05$. The statistical program SPPS ver. 20.0 was used.

3 | RESULTS

On 1 July 2017, 373 type 1 diabetic patients were attending our clinic. They were monitoring their glucose by means of self-measurement of blood glucose (SMBG) (n = 320, 86%), continuous glucose monitoring (CGM) (n = 42, 11%) and FGM (n = 11, 3%). Insulin was delivered either as MDI (n = 276, 74%) or CSII (n = 97, 26%). During the next 2 years, six patients died, 15 moved to another hospital, and 38 new patients were admitted to the clinic. On 1 July 2019, the distribution of the 390 patients attending the clinic was SMBG (n = 45, 12%), CGM (n = 64, 16%) and FGM (n = 281, 72%). There was no change in insulin distribution mode after 2 years; MDI (n = 283, 73%) and CSII (n = 107, 27%). The evolution in the number of patients using the three glucose-monitoring modalities is shown in Figure 1.

In the 2-year period, 326 patients were exposed to FGM. Five patients were initiated on FGM at other hospitals. The characteristics of patients who initiated FGM in our clinic and those who did not are described in Table 1. Patients who initiated FGM had a shorter diabetes duration and were more likely to be treated with MDI than with CGM.

FGM adherence was studied in the 321 patients who had been started on FGM in our clinic. The follow-up period was censored for those who died (n = 4), moved to another hospital (n = 10) or were at the end of the observation period which was 15 October 2019. The follow-up from FGM commencement to censoring was median or 666 days IQR (519-735). The Kaplan-Meir curve is seen in Figure 2. Adherence after 736 days was 88%.

FGM was stopped in 30 patients of whom 12 continued with CGM as an alternative. For 25 cases, termination was on the patient's request for the following reasons: skin reactions (n = 11), frequent accidental loss of sensor (n = 5) and other complaints (n = 9). In addition, five patients were switched to CGM for clinical reasons like hypoglycaemic unawareness or change to an insulin pump with hybrid closed loop.

Among 321 patients started on FGM, efficacy could be studied in only 270 patients for the following reasons: FGM initiated for palliative reasons due to malignant disease (n = 3), invalid HbA1c due to haemodialysis or erythropoietin treatment (n = 2), FGM initiated simultaneously with shift from MDI to CSII (n = 6), FGM initiated in newly diagnosed type 1 diabetes (n = 5), pregnant or lactating (n = 6), systemic steroid treatment at baseline (n = 4), the time from the FGM commencement to the end of the observation period < 6 months (n = 5), termination of FGM before 6 months because the patient stopped FGM (n = 12)

and missing follow-up HbA1c values (n = 8). Glucose monitoring used before FGM was SMBG (n = 268) or CGM (n = 2).

Follow-up HbA1c was the last available HbA1c value obtained before 15 October 2019 or the last value obtained before sudden death (n = 1), moving to another hospital (n = 10), initiating treatment with glucagon-like peptide 1 analogue (n = 1), switching from MDI to CSII (n = 5) or terminating FGM after more than 6 months (n = 13).

Baseline HbA1c was median 63 mmol/mol (IQR 56, 74) (7.9% (IQR 7.3, 8.9)) and final HbA1c 59 mmol/mol (IQR 53, 68) (7.6% (IQR 7.0, 8.4)). The estimated difference final-baseline HbA1c was −4 mmol/mol (95% CI −5, −3) (−0.4% (95% CI −0.5, −0.3)), $P < .001$). The period from baseline HbA1c to commencing FGM was median 12 days (IQR 4, 48). The period from starting FGM to follow-up HbA1c was median 562 days (IQR 417, 662). Paired HbA1c was HPLC (n = 255) or POCT values (n = 15). The median number of scans was 11 per days for the preceding 90 days (IQR 8, 13) as recorded in 140 patients. Results stratified for different intervals of baseline HbA1c values revealed no statistical significant change in patients with HbA1c ≤ 53 mmol/mol (7.0%). However, we observed a significant reduction in the group 53 mmol/mol (7.0%) <HbA1c ≤ 70 mmol/mol (8.6%) and for those with HbA1c larger than 70 mmol/l as seen in Table 2, which also gives results for alternative stratifications to allow comparison with other studies.

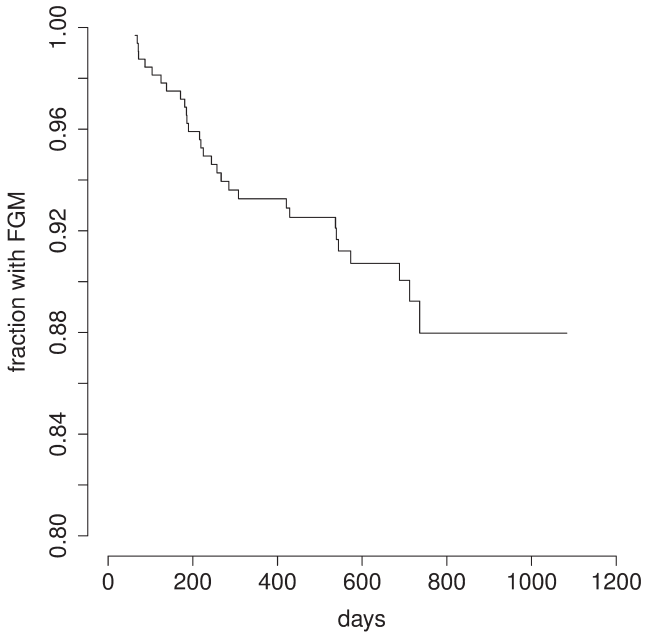

FIGURE 2 Kaplan-Meir analysis of the adherence to FGM for 321 individuals

Among patients who did not initiate FGM (n = 85), 72 used the same method for glucose monitoring and insulin delivery throughout the entire observation period; SMBG, MDI (n = 31), CGM, MDI (n = 5) or CGM, CSII (n = 36). For these patients, the interval between the first HbA1c 58 mmol/mol (IQR 51, 66) (7.4% (IQR 6.8, 8.2)) and the last HbA1c 58 mmol/mol (IQR 51, 67) (7.4%, IQR 7.4, 8.3)) was median 698 days (IQR 541, 739). The estimated difference last − first HbA1c was median 1 mmol/mol (95% CI −1, 3) (0% (95% CI −0.1, 0.2)) ($P = .33$).

The number of scans per day for the past 90 days correlated negatively with final HbA1c (rho = −0.47, $P < .001$) but also with baseline HbA1c (rho = −0.39, $P < .001$). No correlation was noted with number of scans and the difference final − baseline HbA1c (rho = −0.04, $P = .64$).

4 | DISCUSSION

We believe that our study is the first to demonstrate the effect of unlimited access to FGM and one of the longest follow-up studies of FGM reported so far. The principal finding is that a very large fraction of patients were using FGM at the end of the observation period, and except for those with optimal glycaemic control at baseline, they all achieved significantly lower HbA1 levels.

TABLE 2 Changes in HbA1c stratified for categories of baseline HbA1c level

Baseline HbA1c category	Baseline HbA1c (IQR)	Final HbA1c (IQR)	Final-baseline HbA1c estimated difference (95% CI)	*P* value
HbA1c ≤ 53 mmol/mol (n = 44)	51 mmol/mol (47, 52)	49 mmol/mol (46, 55)	1 mmol/mol (−2, 3)	.67
HbA1c ≤ 7.0%	6.8% (6.5, 6.9)	6.6% (6.4, 7.2)	0% (−0.1, 0.2)	
53 < HbA1c ≤ 70 mmol/mol (n = 138)	60 mmol/mol (57, 64)	57 mmol/mol (53, 63)	-4 mmol/mol (−5, - 3)	<.001
7.0 < HbA1c ≤ 8.6%	7.6% (7.4, 8.0)	7.4% (7.0, 7.9)	-0.3% (−0.4, −0.2)	
HbA1c > 70 mmol/mol (n = 88)	79 mmol/mol (74, 85)	73 mmol/mol (64, 80)	-8 mmol/mol (−11, −6)	<.001
HbA1c > 8.6%	9.3% (8.9, 9.9)	8.8% (8.0, 9.5)	-0.7% (−1.0, −0.5)	
HbA1c < 58 mmol/mol (n = 88)	54 mmol/mol (50, 56)	51 mmol/mol (47, 57)	-2 mmol/mol (−3, 0)	.041
HbA1c < 7.5%	7.1% (6.8, 7.3)	6.8% (6.5, 7.3)	-0.1% (−0.2, 0)	
58 ≤ HbA1c ≤ 75 mmol/mol (n = 124)	64 mmol/mol (61, 70)	61 mmol/mol (55, 67)	-4 mmol/mol (−5, −3)	<.001
7.5 ≤ HbA1c ≤ 9.0%	8.0% (7.7, 8.6)	7.7% (7.2, 8.3)	-0.4% (−0.5, −0.2)	
HbA1c > 75 mmol/mol (n = 58)	83 mmol/mol (79, 91)	76 mmol/mol (67, 87)	-10 mmol/mol (−13, −6)	<0.001
HbA1c > 9.0%	9.7% (9.4, 10.5)	9.1% (8.3, 10.1)	-0.9% (−1.2, −0.5)	

Adherence was close to 90% after 2 years of FGM, which shows a high degree of patient satisfaction. Some patients discontinued treatment because of skin reactions. The chemical agent responsible for these reactions has been identified as isobornyl acrylate,[5] and we expect that even higher adherence might be achieved if an adhesive material without this substance is introduced. Patients who discontinued FGM and continued with a CGM stand-alone solution were offered a sensor system without the sensitizing agent.[6]

The main limitation of any 'real life' study like the present is its lack of a control group. Surprisingly, no randomized study exists that reports the effect of FGM in patients with suboptimal control. So far, the only study of unselected adult patients with type 1 diabetes is a recent study from Scotland,[4] which differs from the present study in several respects. It was much larger, including 900 patients, both previously self-funded patients (n = 354) and patients initiated on FGM with NHS funding. The final HbA1c value was missing for 156 patients. The time from commencement of FGM to final HbA1c assessment was not reported. The median interval between the last HbA1c value obtained before initiating FGM and the final HbA1c value was 245 days.

We found that the effect of FGM was largest in the group with the highest HbA1c at baseline, which is in accordance with previous reports.[4,7-9] Regression towards the mean may contribute to this phenomenon. The effect size was comparable with that reported in the study from Scotland,[4] except for the fact that we found a lower HbA1c reduction (−10 mmol/mol (- 0.8%) vs. −14 mmol/mol (−1.3%)) in patients with baseline HbA1c > 75 mmol/mol (9.0%). We excluded patients with newly diagnosed diabetes and patients who switched from MDI to CSII simultaneously with FGM initiation. The large reduction in HbA1c in patients with HbA1c > 9.0% (75 mmol/mol) in [4] may possibly be explained by other interventions than FGM.

HbA1c was not reduced in patients with baseline HbA1c < 53 mmol/mol (7.0%). A slight increase in HbA1c might have been expected [8] because hypoglycaemic episodes might have been detected earlier and corrected. Randomized control trials in patients with good glycaemic control have clearly demonstrated reduced time in the hypoglycaemic range without a simultaneous increase in HbA1c.[1,2]

The lack of control groups is important since we cannot account for any unnoticed time-dependent confounding factor that may have improved the general level of glycaemic control. It is reassuring that HbA1c remained stable in the group of patients who did not alter glucose-monitoring modality (SMBG or CGM) or method of insulin delivery during the entire study period. This observation strengthens the notion that FGM per se improved glycaemic control for a very long period.

Another major drawback is the retrospective collection of data which per definition are vulnerable to bias and selection. Only a minority of patients have HbA1c values from the same day they initiated FGM, and the final HbA1c value was not obtained at a prespecified time interval from initiating FGM but was the last value measured for clinical purpose.

Another point of critique is that we did not include data from patients who discontinued FGM before 6 months and that the follow-up HbA1c value was the last FGM value for patients who stopped after more than 6 months. Theoretically, patients with no positive effect of FGM could be overrepresented in these groups. First, the fraction of patients who stopped before 6 months was small (n = 12) compared with the fraction of patients who continued (n = 321); the same counts for patients who stopped after 6 months (n = 18). Second, none of the patients stopped because of lack of effect on HbA1c; they stopped primarily due to skin reactions and annoying loss of sensors. Third, 40% of patients who stopped FGM continued with CGM; and for these patients, the follow-up HbA1c represents the effect of CGM rather than that of FGM. Without excluding these patients, an attempt to make an 'intention-to-treat' analysis will be flawed.

We studied the quality-of-life aspect only indirectly by reporting adherence rates. Several studies report favourable data from quality-of-life questionnaires in FGM users.[4,9] Increased satisfaction with diabetes treatment is not restricted to patients whose HbA1c levels improve.[1,2]

The study also has some advantages. We scrutinized data files for each of the 411 patients attending our clinic in order to identify all FGM users, and we extracted detailed information about clinical conditions disqualifying patients from inclusion in the follow-up because no control group exists. Among these conditions were newly diagnosed type 1 diabetes, commencing FGM simultaneously with change from MDI to CSII, and pregnancy or lactating at baseline. We had knowledge of the exact date for initiating FGM and were capable of identifying patients who used FGM for more than 6 months. Furthermore, patients who switched from FGM to CGM in the follow-up period and the date of this transition were identified. Such information would inevitably be missing in studies with an epidemiological approach.

The use of real-world data implies that also patients who are not likely to participate in randomized studies are included in the analysis. This encompasses patients who seldom respond to written invitations and often miss appointments. During 2 years, we had the opportunity to approach all patients as they showed up in the clinic and to discuss FGM with them. For those who were interested, FGM could often be started right away after a short instruction and they did not need to participate in a formal course. This may explain the high fraction of users (72%) in our clinic still using FGM at the end of the study period as compared with the study from Scotland (31%) who invited patients per letter.[4] Since FGM users represented 86% of all patients without CGM at the end of the 2-year period in the present study, we believe that our study reports generalizable effects of truly unrestricted access to FGM.

No recommendations of the optimal frequency of scanning exist. In Scotland, patients were asked to scan more than 6 times per day.[4] In other studies, the recorded number of scans was 8-9 scans per day [8] or 9-10 scans per day.[10] We arbitrarily recommended more than 10 scans per day. This goal was largely achieved as judged from the subset of patients with information about scanning frequency. A cross-sectional study of data uploaded from more than 50.000 readers to a database reports a median of 14 scans per day.[3] This number may be biased if patients uploading data are particularly motivated

and perform an extraordinarily high number of scans. In addition, a very clear association between a high number of scans and low HbA1c estimated from the scanned glucose values was shown in this [3] and other studies.[8,9] It is unknown if this reflects a causative relation or merely an association between a high number of scans in patients with excellent self-care and competing explanations for good glycaemic control. Although interpreted with caution due to low numbers, our findings are in favour of the latter explanation, since we found no correlation with scan frequency and change in HbA1c. In contrast, a significant, negative correlation was seen between final but notably also between baseline HbA1c and number of daily scans. This implies that patients with good glycaemic control at baseline are more likely to perform a high number of scans when FGM is initiated. It can be speculated if a good habit of frequent self-monitoring is continued when switching from SMBG to FGM. Besides the baseline level of HbA1c, the reduction of HbA1c must depend on other skills than scan frequency. This could be prudent interpretation of the 24h glucose profile, active use of glucose tendency arrows, correct timing of meal insulin, carbohydrate count, etc It has been shown that FGM users benefit from participating in a formal learning setting focused on these issues.[10] While the scan frequency seems not be of paramount importance for the change in HbA1c within the range of scanning frequency examined in the present study, the same may not be true if the objective is to prevent hypoglycaemia. The subject of optimal scanning frequency may be become less important in the future if glucose values transmitted as near-field communication are combined with blue tooth technology. In that case, the distinction between FGM and CGM will level out.

A crucial issue when new promising technology is launched is how patients get unrestricted access to this technology independent of personal economy, social status or reimbursement rules set up to minimize cost for society as presently seen in Denmark in contrast to most of our neighbouring countries. The policy of free access to FGM in our clinic was stopped because we had to follow the national instruction to introduce FGM only in adults with very poor glycaemic control.

In conclusion, this observational study of unlimited access to FGM in a single centre demonstrates good adherence to FGM and a clinically significant long-term improvement for patients with SMBG who are in nonoptimal glycaemic control. There is, however, no logical reason to decline FGM reimbursement for patients with optimal glycaemic control. First, this group of patients often has obtained the goal because of a very high number of SMBGs, a burden that can be relieved with FGM; second, they will profit from reduced time spent in hypoglycaemia as shown by other studies. SMBG is still needed for occasionally confirmative glucose measurement and for calibration of some CGM sensors. Otherwise, the era of SMBG as the major modality for glucose monitoring in type 1 diabetes is past, as illustrated in this study.

ACKNOWLEDGEMENTS

I am grateful for the assistance of Andrew Bolas with data management and of statistician Asger Roer Pedersen for help with Figures 1 and 2.

CONFLICTS OF INTEREST

None.

DATA AVAILABILITY STATEMENT

The data that supports the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Hansen KW. Effects of unrestricted access to flash glucose monitoring in type 1 diabetes. *Endocrinol Diab Metab*. 2020;3:e00125. https://doi.org/10.1002/edm2.125