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CGM Versus FGM; or, Continuous Glucose Monitoring Is Not Flash Glucose Monitoring

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Background

A number of different systems for real-time continuous glucose monitoring (CGM) have been available for approximately 10 years. To date, relatively few patients in Germany (<2000) use CGM on a long-term basis—in particular due to the arguably considerable costs. Based on the final benefit assessment by the IQWiG (Institute for Quality and Efficiency in Health Care), we expect approval to be granted for cost reimbursement by the Gemeinsamen Bundesausschuss (Joint National Committee) at the end of 2015/beginning of 2016. Across the board cost coverage is not assumed. Rather, patient groups with specific indications which demonstrably profit from CGM can expect cost reimbursement upon meeting documentation requirements.

Autumn 2014 saw Abbott bring to the market the Freestyle Libre—a new option in glucose monitoring: The manufacturer calls this a flash glucose monitoring (FGM) system, most probably this will be the abbreviation to remember as it will be used widely in the future. This device is based on the further technological development of the Freestyle Navigator CGM system by the same manufacturer. In contrast to the currently available CGM system the FGM system does not require calibration, that is, the production technology is so highly developed that a factory calibration is possible. So far, this CE-marked medical product is only available on the European market (and that only in a few countries); market approval by the Food and Drug Administration in the United States is being sought. Based on this background this commentary is aiming to summarize our current experience with FGM versus CGM in Germany, taking many different factors into consideration.

Interested patients can order the FGM device on the Internet (www.freestylelibre.de). As the FGM is not covered by statutory health insurance, to date, patients themselves have covered the costs. There are currently no recommendations or guidelines for the use of FGM specified by the German Diabetes Association.

It is remarkable how much media interest has been generated by a rather limited marketing campaign. The high patient interest has resulted in a stop in taking on new customers; the manufacturer has used the available delivery capacities to supply sensors to existing customers. New patients are being taken from a waiting list. The limitations in delivery capacities will be overcome sooner than later.

Patients using the device are apparently very satisfied with its performance (numerous reports are available in patient blogs). It appears as if the patients have no problems, when adjusting insulin doses based on the FGM values ("replacement claim"). It is of interest to note that clinical decisions are made on the FGM data, something that is not approved until now with other CGM systems. This is the way the system is marketed in EU. However, in the manual the manufacturer stated, "with the exception of following situations the device can replace BG measurements . . . : rapid changes of glucose, confirmation of hypoglycemia, displayed value is not in accordance with symptoms." Nonetheless there are no clear recommendations for the use of FGM instead of BG, for example, by expert associations. Experienced clinical colleagues report positive experience with FGM.

In the meantime, many publications and the results from a series of meta-analyses support the clinical benefit of CGM.[1,2] Results from scientific studies on metabolic and psychological effects resulting from the use of FGM have not yet been published, that is, there is no evidence to date for the benefit of FGM. The manuscript from a precision study performed in the United States required for CE marking was published recently (based on relatively short-term use of FGM by patients with type 1 and type 2 diabetes), in this study the performance of the FGM was evaluated versus a laboratory method.[3] Unfortunately no data from a head-to-head study against a CGM system were published until now. The results from 2 in-progress European, multicentric clinical studies (IMPACT and REPLACE) of longer study duration (one for type 1 and one for type 2) are expected at the end of 2015.

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Table 1. Differences Between CGM and FGM.

Provider (procurement option)	Several	One
Calibration	Daily	Factory calibrated by the manufacturer
Lancing required	Yes[a]	No[b]
Sensor insertion under the skin required	Yes	Yes
Form required for cost absorption	Yes	Basically not currently covered by the National Association of Statutory Health Insurance Funds
Statements on this topic on the Internet	Yes	Many
Glucose measurement in ISF, not in blood	Yes	Yes
Maximum duration of sensor use	7 days	14 days
Test result displayed on an external device	Yes (also insulin pump)	Yes
Permanent connection to an external device	Yes	No
(Hypo) alarms	Yes	No
Current value displayed	Yes	Yes
Trend arrow displayed	Yes	Yes
Adjustment of the insulin dose based on test results	Not to date	Yes (limited)
BG replacement claim	No	Yes (with exceptions in special situations)
Connection to pump	Yes (most systems)	No
Usability with artificial pancreas	Yes	No (at this current technological state)
User	Type 1	Type 1 and type 2
Number of users	Rather few	Many ("mass-produced product")
Applicable for/usable in children	Yes	No
Emotionality in patients	Moderate	Strong
Media response	Low	High
Increase in quality of life	Moderate to high	High
Doctor knowledge	Low	Low
Diabetologist knowledge	Present	Currently increasing
Recommended by diabetologists	Yes	Currently increasing
Training sessions required	Yes	Yes
Manufacturer-independent training program	Not available (available: end of 2015)	The manufacturer has created a program
Evidence	Strong	Not yet strong
Costs per day	ca 10 (without calibration)	ca 5
Cost absorption	In justified individual cases Likely soon To date self-payers	By some health insurance companies (future?) Otherwise self-payers
Data transfer of anonymous data	No (insofar as known)	Yes (according to manufacturer statements)
Perception by cost carriers	Low	High
Costs saved in comparison to costs of test strips)	No	Possible (depending on the test frequency)

[a]Blood glucose test for calibration purposes.
[b]Manufacturer statement: "An additional check of glucose values using a blood glucose meter is required for rapidly-changing glucose levels as the glucose values in the tissue fluid may not exactly reflect the blood glucose values, or if the system displays a hypoglycemia or a pending hypoglycemia."

These studies aim to clarify whether the use of FGM offers advantages in comparison to conventional blood glucose testing for the primary endpoints HbA1c, and respectively, hypoglycemia. Additional important aspects for practical use will be evaluated as secondary endpoints. These studies will also be of help with respect to the replacement claim. There are also older publications that deal with the principle characteristics of the glucose measurement technology used in the FGM system, albeit the FGM system was not completely evaluated in its market-ready state.[4-6]

Table 1 displays the differences between CGM and FGM. In addition to the technical differences, various factors are included which are of relevance to positioning both these approaches.

Positioning of FGM

The manufacturer positions FGM as a "third" category that corresponds to neither a CGM system nor a conventional blood glucose (BG) meter. In principle, FGM could replace the "BG meters": The painful finger lancing for obtaining a

blood drop becomes unnecessary—an important argument from a patient perspective—and, while correctly performing BG self-monitoring takes a few minutes, FGM reads the results (maximum the last 8 hours) using the scan option within a few seconds—a major difference in handling effort required on a daily basis.[7] Such aspects have simply added to the high level of interest patients have displayed toward FGM.

FGM enables a low-threshold entry into what is clearly "more information": Even if the glucose measurements are not constantly updated (as in CGM) and therefore no instant alarms are triggered when defined limit values are exceeded, the current glucose value is quickly available if needed. In addition, the glucose change trend is shown using an arrow and a graph shows the glucose profile over the previous hours. This new and additional information is new to many patients and their attending doctors and presents a challenge for untrained patients as they do not adequately know how to therapeutically deal with this information. The manufacturer offers specially developed training sessions for specialist personnel on these topics and plans to offer a certified training as well.

CGM has so far primarily been used by well-informed and properly trained patients with type 1 diabetes whereby FGM users appear to include patients with type 2 diabetes who have performed only few BG measurements per day and are now, for the first time, seeing how their BG rises after a meal or lowers resulting from physical exercise. For long-term CGM users, the immediate availability of reliable information about their metabolic state which also has adjustable alarms is an important—even indispensable—part of their diabetes therapy. There are also patients who feel the alarms are bothersome; FGM is certainly an option for these patients.

Cost Aspects and Cost Carrier Response

Currently, the costs of FGM in Germany are approximately 50% less than for CGM but not much more than BG self-monitoring (at 6-8 BG tests per day, depending on the basic test strip costs). Such statements indeed present some incertitude due to the differing prices calculated for test strips, the period of "consumables" use time (14 days for FGM, officially ca 7 days for CGM, in practice often longer) and the rather low costs for the FGM reader or the high costs for the CGM handheld devices.

Cost reimbursement for CGM by the cost carriers has only been granted on an individual basis (see above). The high level of patient interest in FGM has led cost carriers to give concrete thought to absorbing the costs of FGM (based on the statements issued by the health insurance companies: Techniker Krankenkasse, DAK-Gesundheit, BIG direkt gesund-Krankenkasse). The costs for FGM appear to no longer be seen prohibitively by the cost carriers. The health insurance companies thereby also seem to positively evaluate this possibility for frequent testing current glucose concentrations. This in turn can be interpreted that the insurance companies see an advantage in high frequency testing which is possible with FGM without additional costs. The benefit of doing so with conventional capillary self-measurement of BG has been shown several times, also recently.[8,9]

Summary

It remains to be seen as to what share of the market FGM will achieve if the manufacturer can supply any amount desired. Will a significant portion of the glucose monitoring market then be taken over by FGM? The availability of FGM as a new option for glucose monitoring can basically be evaluated positively and it does indeed clearly show the benefit of "more information" on the glucose trend. The relatively low price for glucose monitoring using FGM and the unusual market introduction (not first via the National Association of Statutory Health Insurance Funds, as was the case with CGM) have given increased attention to the use of more glucose information. It will likely take a certain amount of time before other providers are able to bring different FGM systems to the market.

The option of coupling a CGM system with an insulin pump offers the perspective of an automated insulin application, that is, a closed-loop system. Such systems are currently being tested under everyday conditions, although it is not possible to predict when they will actually reach the market. There are, however, such couplings where algorithms are responsible for shutting off insulin delivery when the glucose concentration reaches a defined level or if it will be reached in the foreseeable future. This significantly helps prevent hypoglycemia. These options are only available with CGM.

The aim of this commentary is to present the differences between CGM and FGM, including the advantages and disadvantages of both approaches. We see significant benefits in both options based on the different positioning of the approaches and the different user groups.

Abbreviations

BG, blood glucose; CGM, continuous glucose monitoring; FGM, flash glucose monitoring; ISF, interstitial fluid.

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chairs an advisory board for Abbott Diabetes Care in Germany about FGM. GF is general manager of the Institute für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft an der Universität Ulm, Ulm, Germany, which carries out studies on the evaluation of BG meters and medical devices for diabetes therapy on behalf of various companies. GF is a consultant for a range of companies that develop medical devices for diabetes therapy. GF is a member an advisory board for Abbott Diabetes Care in Germany about FGM.

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