Effectiveness of FreeStyle Libre Flash Glucose Monitoring System Observed in Real-World, Chart Review Study in Adults with Type 2 Diabetes

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Sponsored by
Abbott Diabetes Care

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1. Background

This was a retrospective, non-interventional chart review study collecting HbA1c data from medical records of adults with Type 2 diabetes using FreeStyle Libre Flash Glucose Monitoring System.

2. Aims

The primary aim of the study was to determine the effectiveness of FreeStyle Libre Flash Glucose Monitoring System on glycaemic control, measured by HbA1c, using lab data collected from patient records.

3. Study Design and Inclusion Criteria

- The study was submitted to Ethics Committees for review and anonymised data was collected for the study.
- Study was conducted at 6 secondary care medical centres across Germany using current patient medical records.
- Information was extracted from medical records (paper/electronic) to describe the two periods prior to and between 3 and 6 months after initiation of FreeStyle Libre.
- HbA1c data was collected during a baseline period (SMBG use) and compared to HbA1c after 3-6 months of FreeStyle Libre use (within patient analysis).
- To minimise selection bias, **all eligible patients** that had used FreeStyle Libre since 2014 were included in data collection.

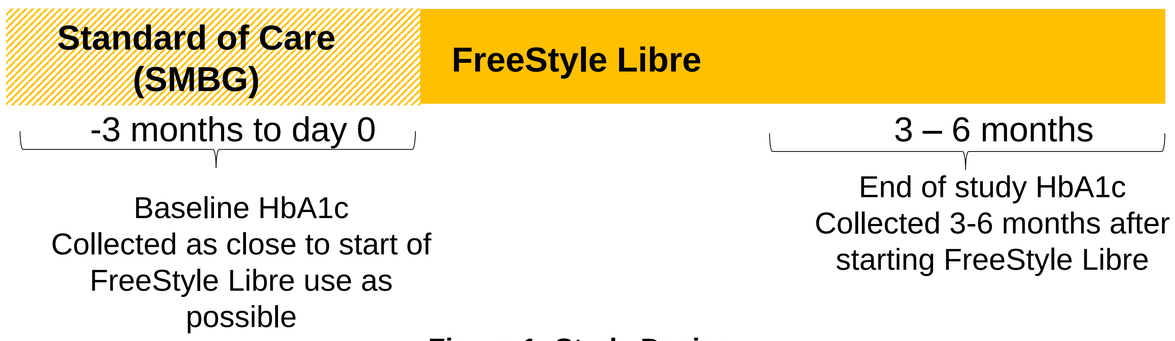

Figure 1: Study Design

Inclusion Criteria were:

- Aged 18 years or over.
- Type 2 diabetes using basal-bolus insulin regimen for at least 1 year.
- Had used the FreeStyle Libre System regularly for at least 3 months.
- HbA1c recorded in medical notes between 8.0% and 12.0% (64-108 mmol/mol) in the 3 months (90 days) prior to starting FreeStyle Libre.
- HbA1c recorded in medical notes 3 to 6 months (90 to 194 days) after starting FreeStyle Libre. If more than one HbA1c result fitted the inclusion criteria, the test closest to 135 days after starting FreeStyle Libre was used for analysis.

Exclusion Criteria were:

- Female participant who was pregnant during the data collection period.
- Received dialysis treatment during the data collection period.
- Participated in another device or drug study that could have affected glucose measurements or management during the data collection period.

A total of 2698 records were screened and 213 records were recorded and received.
183 records met the inclusion criteria and were included in the endpoint analysis.

Table 1: Medical Record Accountability

	Total
Records Received	**213**
Did not meet Inclusion/Exclusion Criteria	8*
Did not have a baseline HbA1c within 3 months (90 days) of starting FreeStyle Libre	4
Did not have a HbA1c result 3 to 6 months after starting FreeStyle Libre	18
Total Number included in Primary End point analysis	**183**

** 1 met exclusion criteria, 6 had <1 year insulin use, 1 baseline HbA1c >12%*

4. Demographics and Baseline Characteristics (n=183△)

Table 2: Baseline Demographics

Sex n=182*		Age	BMI	Duration of Insulin Use n=176▫	Baseline HbA1c	
Male	Female	(years)	(kg/m^2)	(years)	(%)	(mmol/mol)
104 (57.1%)	78 (42.9%)	62.7 ± 11.8 [28, 86]⬩	33.8 ± 6.9 [21.0, 77.7] ⬩	7.8 ± 5.4 [1, 27] ⬩	8.9 ± 0.9 [8.0, 12.0] ⬩	73.1 ± 10.3 [64, 108] ⬩

△unless otherwise stated. * 1 sex not stated ⬩mean ± SD [minimum, maximum]
▫7 medical records did not state the start date of Insulin use

Patients were on a basal-bolus insulin regimen using multiple daily injections (MDI, n=182) or insulin pump (n=1).

4. Demographics and Baseline Characteristics cont

Patient medical history included complications arising from cardiovascular disease (n=64, 35.0%), renal disease (n=65, 35.5%), retinopathy (n=28, 15.3%), foot ulcer (n=17, 9.3%), cataract (n=10, 5.5%), macular oedema (n=4, 2.2%) and neuropathy (n=116, 63.4%)

Patient medications at time of starting FreeStyle Libre were Metformin (n=99, 54.1%), SGLT-inhibitors (n=50, 27.3%), DPP4 inhibitors (n=39 21.3%) and Sulphonylureas (n=1, 0.5%). Additional diabetes medications taken were GLP-1 agonists (n=21, 11.5%)

5. Primary endpoint: Change in HbA1c

Primary endpoint analysis evaluated change in HbA1c at 3 to 6 months (90 to 194 days) after initiation of FreeStyle Libre from Baseline. There was a significant reduction in HbA1c after using FreeStyle Libre.

Start of patient FreeStyle Libre use was between September 2015 and August 2018. Analysis includes medical records dated from July 2015 until December 2018.

Table 3: Change in HbA1c (%) at 3 to 6 months after FreeStyle Libre Wear versus Baseline.

Measure	N	Baseline Mean ± SD	Final Phase (days 90-194) Mean ± SD	Change Mean ± SD	95% CI for Change	P-Value
HbA1c (%)	183	8.9 ± 0.9	7.9 ± 0.9	-0.9 ± 1.1	(-1.1,-0.8)	<0.0001
HbA1c (mmol/mol)	183	73.1 ± 10.3	63.0 ± 9.6	-10.1 ± 12.2	(-11.9, -8.3)	<0.0001

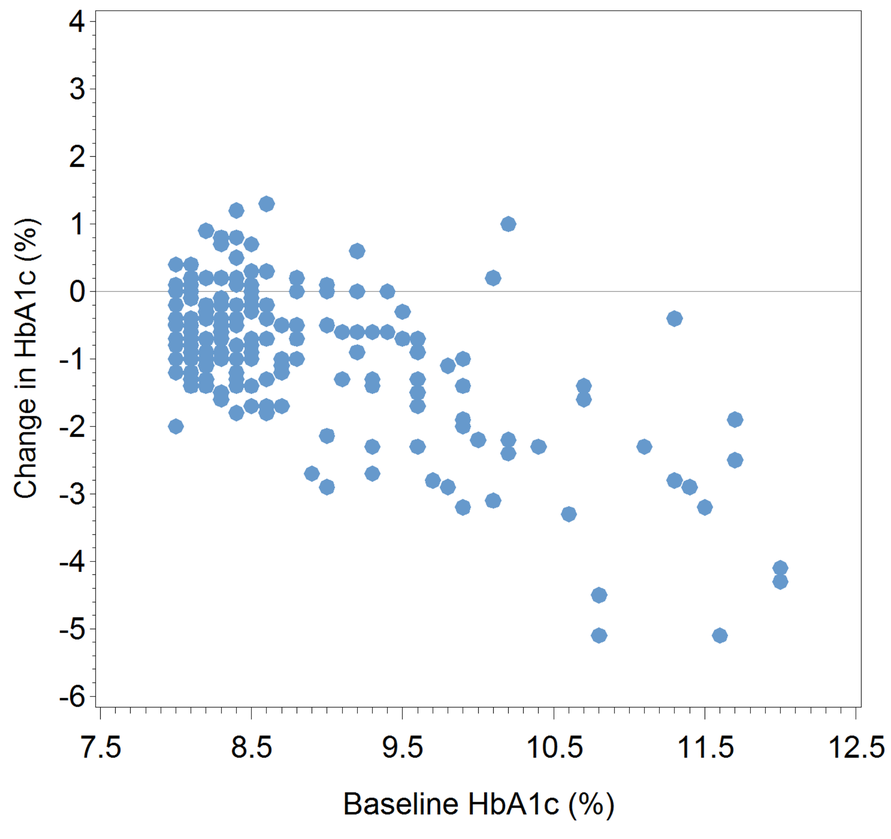

Figure 2: Change in HbA1c (%) between Baseline and Final

6. Sensitivity Analysis on Primary Endpoint

Change in HbA1c with narrower time windows (4 weeks, 8 weeks, 12 weeks) centred around day 135 was analysed. In these analyses, the baseline HbA1c result remained the same.

Table 4: Change in HbA1c (%) Sensitivity Analysis

Days (Final HbA1c)	N	Baseline Mean ± SD	Final Phase Mean ± SD	Change Mean ± SD	95% CI for Change	P-Value
121 to 149	44	9.0 ± 1.0	8.2 ± 1.0	-0.8 ± 1.3	(-1.2, -0.4)	0.0004
107 to 163	87	8.9 ± 1.0	8.0 ± 1.0	-1.0 ± 1.3	(-1.3, -0.7)	<0.0001
90 to 180	170	8.9 ± 1.0	7.9 ± 0.9	-1.0 ± 1.1	(-1.1, -0.8)	<0.0001

7. Conclusions

This real-world, chart review study concluded that adults in Germany with Type 2 diabetes on insulin therapy using the FreeStyle Libre System for between 3-6 months significantly improved HbA1c.

8. Acknowledgements

We would like to thank the staff at the study sites for their valuable contribution to the studies.