FreeStyle Libre 2
FLASH GLUCOSE MONITORING SYSTEM

THE SELFY STUDY[1,*]

Investigating the outcomes of the FreeStyle Libre 2 System for children & teenagers[1,*]

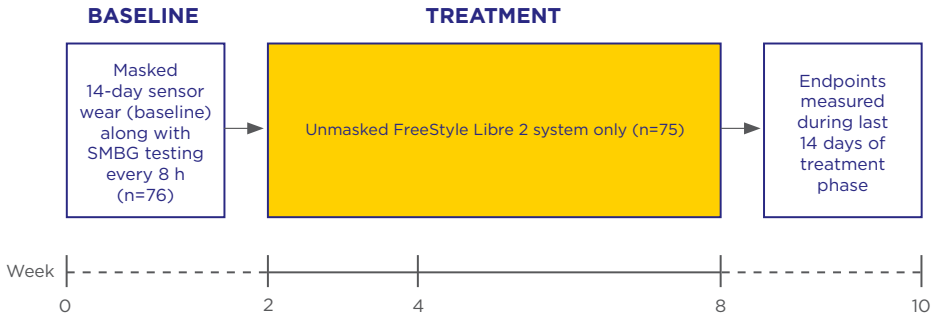
EUROPE

PARTICIPANT PROFILE:

- 76 children and teenagers (4-17 years) with type 1 diabetes treated in specialist diabetes centers in Europe
- Type 1 diabetes diagnosis > 1 year
- Self-monitored blood glucose (SMBG) testing ≥ 2 times per day on average
- 42% on multiple daily injection (n=32), 58% on continuous subcutaneous insulin infusion (n=44)
- Suboptimal mean baseline HbA1c of 7.9±1.0%

RESEARCH DESIGN:

An 8-week, prospective, multicenter, open-label, non-inferiority, single-arm treatment study



Day 29: Glycemic control and sensor data reports were reviewed with a healthcare professional

OUTCOMES

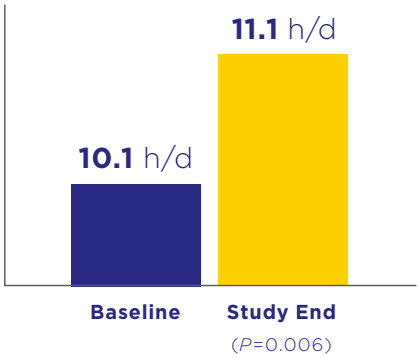
Primary: Equivalence of continuous glucose monitoring (CGM) vs SMBG in time in range (70-180 mg/dL) in children and teenagers (4-17 years) with T1D

Secondary: Change in HbA1c, frequency of scanning vs fingersticks, number and duration of hyperglycemic (>180 mg/dL) and hypoglycemic (<70 mg/dL) events, glucose variability

PRIMARY OUTCOME:

FreeStyle Libre 2 system significantly improved time in range:

1-HOUR IMPROVED TIME IN RANGE



(*P*=0.006)

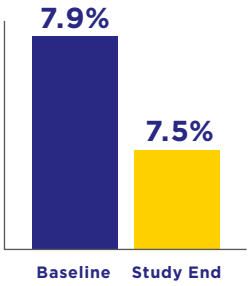
SECONDARY OUTCOMES:

THE SELFY STUDY[1,*]

IMPROVED HbA1c

↓0.4%

improvement for **children and teenagers** with diabetes (age 4 & older) with no significant increase in duration of hypoglycemia (*P*<0.0001)

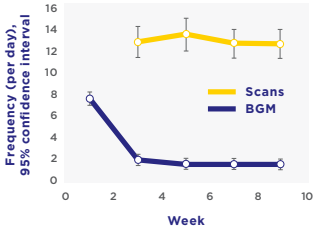


INCREASED SCANNING

~2×

MORE MONITORING

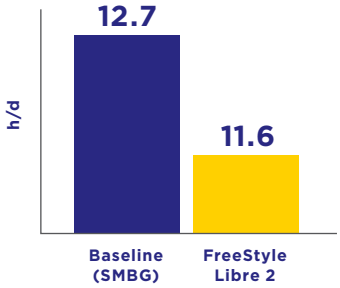
compared to SMBG testing (in-study scanning average 13× per day)



REDUCED TIME IN HYPERGLYCEMIA

↓1.2 h/d

less time spent in **hyperglycemia** (>180 mg/dL) (*P*=0.004)



DIABETES TREATMENT SATISFACTION QUESTIONNAIRE

The use of the FreeStyle Libre* system in children and teenagers with diabetes increased overall parental satisfaction with their diabetes treatment (*P*<0.0001)

For more information about the FreeStyle Libre 2 system, visit Payer.FreeStyleLibre.us

FreeStyle Libre 2 FLASH GLUCOSE MONITORING SYSTEM

MORE PATIENTS CAN DO IT WITHOUT FINGERSTICKS†

life. to the fullest.®

Abbott

* Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore, the study data is applicable to both products.

† Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours.

Reference: 1. Campbell, Fiona M., Nuala P. Murphy, Caroline Stewart, Torben Biester, and Olga Kordonouri. "Outcomes of Using Flash Glucose Monitoring Technology by Children and Young People with Type 1 Diabetes in a Single Arm Study." *Pediatric Diabetes* 19, no. 7 (2018): 1294–1301. https://doi.org/10.1111/pedi.12735.

Indications and Important Safety Information

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older.‡

WARNINGS/LIMITATIONS‡: The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems. Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment. Do not take high doses of vitamin C (more than 500 mg per day), as this may falsely raise your Sensor readings. Failure to use the System according to the instructions for use may result in missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value to make diabetes treatment decisions. Seek medical attention when appropriate and contact Abbott Toll Free (855-632-8658) or visit ‡ www.FreeStyleLibre.us for detailed indications for use and safety information.

‡ Please refer to www.FreeStyleLibre.us for the indications and important safety information.

The circular shape of the sensor housing, FreeStyle, Libre, and related brand marks are marks of Abbott. Other trademarks are the property of their respective owners.

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