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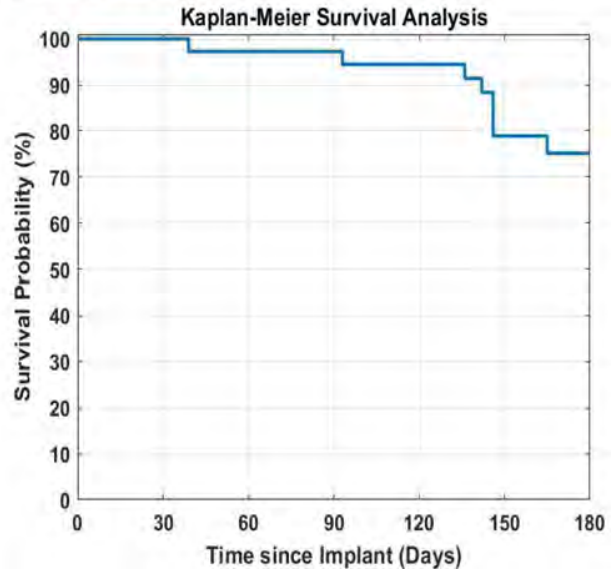
Figure – Kaplan Meier Survival Analysis for Sensor Longevity



23 male, with mean BMI of 22 ± 4. At the interim analysis, 25 sensors had either completed the 180-day follow-up without a replacement alarm or had undergone device removal prior to day 180. At post-implant days 90, 120, 150, and 180, the estimated probabilities of sensor survival were 97%, 94%, 79%, and 75%, respectively (Figure).

Conclusion: The Eversense CGM using a new sensor configuration demonstrates 75% survivability through 180 days of sensor wear.

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Glucose Sensors

ATTD8-0239

NEXT GENERATION DEXCOM SENSOR WITH BAYESIAN ALGORITHM GOES TOWARDS A CALIBRATION-FREE SCENARIO

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Background and Aims: Dexcom continuous glucose monitoring (CGM) devices currently in the market need to be calibrated twice/day exploiting self-monitoring of blood glucose references. Recently, we developed and validated an online Bayesian calibration algorithm able to reduce the frequency of calibrations up to one every four days without worsening sensor accuracy on Dexcom G4 Platinum data. Here, we assess performance of our algorithm on a next-generation Dexcom CGM sensor prototype.

Method: The new Bayesian calibration algorithm is applied to 48 raw signals acquired with a next-generation Dexcom CGM sensor prototype for a 10-day period. By simulating an online setting, we tested progressively less-calibration scenarios, until zero. Accuracy of the calibrated glycemic profiles is evaluated by comparison with blood glucose references via absolute relative difference (ARD) using a cross-validation approach for prior knowledge derivation. We then assessed the algorithm ability to generalize by deriving prior knowledge from a different dataset (55 sensors belonging to a different lot).

Results: In the cross-validation approach, median ARD over all matched-pairs for the different scenarios is 7.5% (one-per-day calibration), 7.3% (one-every-two-days calibration), 7.8% (one-every-four-days calibration) and 9.3% (zero calibrations). Accuracy of the zero-calibration scenario worsens of only 1% when using prior knowledge derived from a different lot of sensors.

Conclusion: The new Bayesian calibration algorithm well performs on CGM data acquired by a next-generation Dexcom sensor prototype, outperforming the current commercial CGM devices, independently from the frequency of calibrations. Moreover, accuracy remains stable when including more variability in sensor-to-sensor characteristics, allowing moving towards a calibration-free scenario.

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Glucose Sensors

ATTD8-0092

SENSOR-AUGMENTED PUMP WITH PREDICTIVE LOW GLUCOSE SUSPEND FUNCTION: IMPACT ON GLYCAEMIC CONTROL IN ADULTS AND CHILDREN

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Background and Aims: To evaluate the effect of sensor-augmented pump with predictive low-glucose suspend function (SAP-PLGS) on glycaemic control and frequency of hypoglycaemia.

Method: All the patients with type 1 diabetes treated with MiniMed 640G® pump with ''suspend before-low'' function at 3 referral hospitals in Spain were retrospectively evaluated. Baseline HbA1c, HbA1c at 3, 6, 12, 18 and 24 months and SAP-PLGS downloads at baseline and last follow-up visit were analysed.

Results: 162 patients had at least 3 months of follow-up, median follow-up: 12 months [6–18], age: 32 ± 17 years, 28% <18 years-old, 62% female. The main indication for SAP-PLGS was frequent hypoglycaemia (57%, n = 92), 29% of the patients had a history of severe hypoglycaemia. Baseline HbA1c dropped from 7.2 ± 0.8% to 7.1 ± 0.7% at 12 months (p = 0.029, n = 100), with no significant differences at 3, 6, 18 and 24 months. Percentage of patients with HbA1c in range increased from 56% to 59% at the last follow-up visit; percentage of SMBG values <70 mg/dl decreased from 10 ± 7% to 6 ± 5%, with no changes in values <54 mg/dl, >180 mg/dl or >250 mg/dl; number of SMBG per day decreased from 7.4 ± 3.2 to 6.6 ± 2.7; bolus insulin increased from 52 ± 14% to 54 ± 13% (all p < 0.01). Sensor use was 6.0 ± 0.8 days/week. Sensor values were compared in the group of patients using CGM before SAP-PLGS (n = 54, median

	Baseline	End of follow-up	p
Hba1c (%)	7.0 ± 0.7	7.1 ± 0.8	0.640
Time < 54 mg/dl (%)	1.2 ± 1.6	0.8 ± 0.9	**0.035**
Time < 70 mg/dl (%)	4.5 ± 3.6	3.1 ± 2.3	**0.001**
Time > 180 mg/dl (%)	30 ± 14	44 ± 74	0.144
Time > 250 mg/dl (%)	6.8 ± 6.4	8.1 ± 7.5	0.160
Mean sensor glucose (mg/dl)	147 ± 29	156 ± 22	**0.034**
SD of sensor glucose (mg/dl)	54 ± 12	53 ± 13	0.579
Sensor use (days per week)	5.6 ± 1.1	5.9 ± 0.9	0.059

n=54. Data are expressed as mean ± standard deviation.

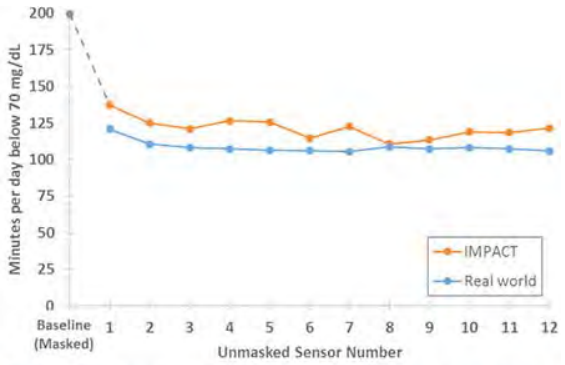

Figure 1 Comparison of longitudinal outcomes between clinical trial and real-world use of the FreeStyle Libre system for individuals at risk for hypoglycaemia.

follow-up: 12 months) (Table 1). Patient satisfaction was high in 73% of patients (n = 80).

Conclusion: Sensor-augmented insulin pump with predictive low glucose suspension reduces time in hypoglycaemia, without worsening glycaemic control, in children and adults in a real-world clinical setting.

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Glucose Sensors

ATTD8-0345

COMPARISON OF FLASH GLUCOSE MONITORING USAGE PATTERNS AND GLYCAEMIC OUTCOMES IN THE REAL-WORLD WITH THOSE OBSERVED IN A RANDOMIZED CONTROLLED TRIAL

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Background and Aims: Flash Glucose Monitoring (Freestyle Libre™ system) use was assessed in the IMPACT study for glycaemic outcomes and scanning patterns over 6 months. Here, we compare real-world data with data from IMPACT in a similar population of individuals with well controlled diabetes.

Method: De-identified glucose data from 4793 users over 6 months (12 sensors) were investigated. Only individuals with an Estimated HbA1c ≤ 7.5% during Sensor 1 wear were included. A comparison of time spent in hypoglycaemia (<70 mg/dL) and time spent in serious hypoglycaemia (54 mg/dL or lower) in consecutive 2 week periods over 6 months was made between real-world and IMPACT data. A comparison of overall scanning frequencies was also made.

Results: Comparing time spent in hypoglycaemia, a reduction of 11% was seen from Sensor 1 to Sensor 12 (from 137 min/day to 122 min/day, p = 0.039) in IMPACT and 12% in real-world data (from 121 min/day to 106 min/day, p < 0.001). A reduction in time spent in serious hypoglycaemia of 13% was seen from Sensor 1 to Sensor 12 (from 55 min/day to 48 min/day, p = 0.112) in IMPACT data and 10% in real-world data (from 48 min/day to 43 min/day, p < 0.001). Overall average scan rates of 15 scans/day were observed in IMPACT and 14 scans/day in real-world data.

Conclusion: Freestyle Libre use in the real world demonstrates similar usage patterns and improvements in hypoglycaemia that were observed in clinical trials in individuals with well controlled diabetes.

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Glucose Sensors

ATTD8-0320

ACCURACY AND PRECISION EVALUATION OF FLASH GLUCOSE MONITORING SENSORS IN DIFFERENT SITES: THE ABDOMEN AND UPPER THIGH COMPARED TO THE UPPER ARM (OUT OF SIGHT)

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Background and Aims: To compare accuracy and precision of FreeStyle® Libre™ (FSL) flash glucose monitoring sensors (Abbott Diabetes Care, Alameda, CA) placed on the upper arm, abdomen and upper thigh.

Method: Twenty-two well controlled (median HbA_{1c} 7.2%; IQR 6.9–7.4) adults with long-standing type 1 diabetes on multiple daily injections (18/22) or insulin pump (4/22) and median BMI of 24.9 kg/m^2 (IQR 23.0–25.6) were included. Three FSL sensors were simultaneously inserted for 14 days on the back of upper arm, abdomen and upper thigh. FSL measurements were compared to capillary blood glucose (BG) measurements (median 6.8/day; IQR 6.3–7.0) obtained with the built-in FSL BG meter.

Results: Overall mean absolute relative difference (MARD) was 11.9%, 18.7% and 12.3% for arm, abdomen (p < 0.0005 vs.