



Evaluation of a percutaneous optical fibre glucose sensor (FiberSense) across the glycemic range with rapid glucose excursions using the glucose clamp



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Introduction

- FiberSense is a real-time continuous glucose monitoring (CGM) system with a percutaneous fibre optic glucose sensor
- CGM systems display greatest inaccuracies in the hypoglycaemic range and with rapid glucose excursions
- Fluorescence glucose-sensing methods as compared with enzymic CGM show greater sensitivity to low concentrations of glucose (1)
- In *in vitro* measurements of the response kinetic of the FiberSense system, no intrinsic sensor lag time was observed with changes in glucose up to $\pm 4\text{mg/dl/min}$ (2).

Objectives

- To evaluate accuracy of the FiberSense system across the glycemic range and with rapid glucose excursions using the glucose clamp as compared with a gold standard reference laboratory method (YSI glucose)
- Assessment of the performance of FiberSense as compared with commercial enzyme-based CGM device

Methods

- 10 healthy subjects wore 2 FiberSense sensors, one at the abdomen and the upper arm respectively and one Dexcom G4 Platinum CGM sensor at the abdomen.
- Following initial calibration phase, blood glucose was maintained at hypoglycemic (2.5 mmol/l), hyperglycemic (13.9 mmol/l) and then euglycemic (5.0 mmol/l) plateaus each for 20 minutes using variable intravenous insulin infusion and 20% dextrose.
- Blood glucose increased or decreased rapidly at a rate of 2 to 4mg/dl/min between glucose plateaus.
- Arterialised venous blood was sampled every 5 minutes from a hand vein kept in a warm box (55°C) and measured on a YSI 2300 STAT glucose analyser.
- Capillary blood (Bayer Contour Plus) was sampled at the middle and end of each glycemic plateau.

Results

Table 1 Mean Absolute Relative Difference (MARD) analysis

	FiberSense abdomen		FiberSense upper arm		Dexcom G4	
	n	MARD	n	MARD	n	MARD
Full range	160	21.1%	200	26.6%	183	29.7%
Euglycemic (3.9-10 mmol/l)	62	19.8%	80	24.9%	89	38.2%
Hypoglycemic (<3.9 mmol/l)	45	26.8%	54	37.6%	15	23.2%
Hyperglycemic (>10 mmol/l)	53	17.8%	66	19.6%	79	21.3%

Table 2 Agreement of system results with YSI readings

System / % within reference	15/15%	20/20%	30/30%	40/40%
FiberSense abdomen	50.6%	66.2%	83.8%	94.4%
FiberSense upper arm	34.5%	49.0%	79.5%	93.0%
Dexcom CGM	39.9%	48.1%	67.8%	77.0%

References;

- Klonoff DC. J Diabetes Sci Technol. 2012; 6(6):1242-50.
- Muller AJ et al. J Diabetes Sci Technol. 2013; 7(1):13-23.

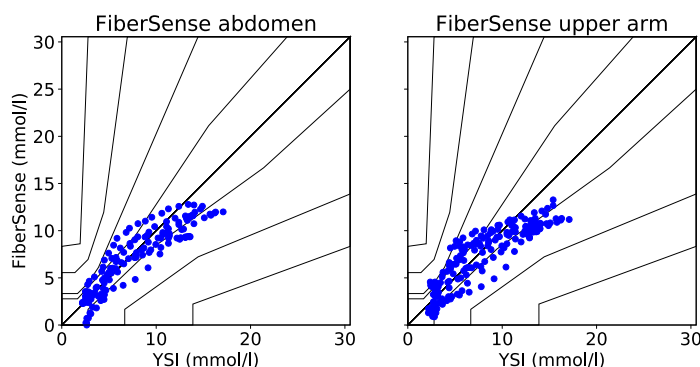


Fig 1 and Table 3 Pooled Consensus Error grid analysis

System / Zone	A	B	(A+B)	C	D	E
FiberSense abdomen	67.5%	31.9%	99.4%	0.6%	0.0%	0.0%
FiberSense upper arm	47.0%	49.0%	96.0%	4.0%	0.0%	0.0%
Dexcom CGM	55.2%	41.0%	97.2%	3.8%	0.0%	0.0%

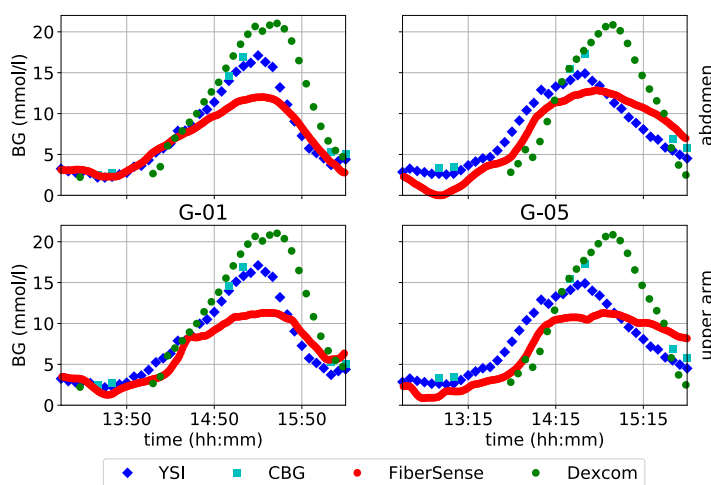


Fig 2 Example of FiberSense glucose profile from abdominal and upper arm sensor sites in two individuals (G-01 and G-05) as compared with YSI, Dexcom G4 and capillary blood glucose (CBG) after calibration during rapid blood glucose change.

Table 4 Accuracy with rapid rate of change (ROC)

	FiberSense abdomen		FiberSense upper arm		Dexcom G4	
	n	MARD	n	MARD	n	MARD
Rapid rise (mean ROC 3 mg/dl/min)	70	20.3%	84	23.6%	81	24.1%
Rapid descent (mean ROC -3 mg/dl/min)	48	18.5%	62	24.0%	73	41.4%

Conclusions

- The FiberSense system is comparable in accuracy to existing commercial enzyme-based CGM systems across the glycemic range.
- With rapid descent in glucose, the FiberSense system displays superior accuracy which is important in the prediction of impending hypoglycemia.
- Studies are currently under way to evaluate the system for extended 28 day home use in diabetes patients.