Journal of Diabetes Science and Technology
Volume 7, Issue 1, January 2013

SYMPOSIUM

Acute *In Vivo* Performance Evaluation of the Fluorescence Affinity Sensor in the Intravascular and Interstitial Space in Swine

Ralph Dutt-Ballerstadt, Ph.D.,[1,2] Colton Evans, B.S.,[1] Arun P. Pillai, M.S.,[1] Ashok Gowda, Ph.D.,[1] Roger McNichols, Ph.D.,[1] Jesse Rios, B.S.,[2] and William Cohn, M.D.[2]

Abstract

Objective:

We assessed and compared the performance levels of a fiber-coupled fluorescence affinity sensor (FAS) for glucose detection in the intradermal tissue and intravascular bed during glucose clamping and insulin administration in a large animal model.

Research Design and Methods:

The FAS (BioTex Inc., Houston, TX) was implanted in interstitial tissue and in the intravenous space in nondiabetic, anesthetized pigs over 6–7 h. For intradermal assessment, a needle-type FAS was implanted in the upper back using a hypodermic needle. For intravenous assessment, the FAS was inserted through a catheter into the femoral artery and vein. Blood glucose changes were induced by infusion of dextrose and insulin through a catheterized ear or jugular vein.

Results:

Based on retrospective analysis, the mean absolute relative error (MARE) of the sensor in blood and interstitial tissue was 11.9% [standard deviation (SD) = ±9.6%] and 23.8% (SD = ±19.4%), respectively. When excluding data sets from sensors that were affected by exogenous insulin, the MARE for those sensors tested in interstitial tissue was reduced to 16.3% (SD = ±12.5%).

Conclusions:

The study demonstrated that the performance level of the FAS device implanted in interstitial tissue and blood can be very high. However, under certain circumstances, exogenous insulin caused the glucose concentration in interstitial tissue to be lower than in blood, which resulted in an overall lower level of accuracy of the FAS device. How significant this physiological effect is in insulin-treated persons with diabetes remains to be seen. In contrast, the level of accuracy of the FAS device in blood was very high because of high mass transfer conditions in blood. While the use of the FAS in both body sites will need further validation, its application in critically ill patients looks particularly promising.

J Diabetes Sci Technol 2013;7(1):35–44

Author Affiliations: [1]BioTex Inc., Houston, Texas; and [2]Texas Heart Institute, Houston, Texas

Abbreviations: (BG) blood glucose, (FAS) fluorescence affinity sensor, (FRET) fluorescence resonance energy transfer, (MARE) mean absolute relative error, (SD) standard deviation

Keywords: concanavalin A, fluorescence affinity sensor, glucose monitoring, hollow fiber

Corresponding Author: Ralph Dutt-Ballerstadt, Ph.D., BioTex Inc., 8058 El Rio St., Houston, TX 77054; email address ralph@biotexmedical.com