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A Disposable Tear Glucose Biosensor—Part 2: System Integration and Model Validation

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Abstract

Background:

We presented a concept for a tear glucose sensor system in an article by Bishop and colleagues in this issue of *Journal of Diabetes Science and Technology*. A unique solution to collect tear fluid and measure glucose was developed. Individual components were selected, tested, and optimized, and system error modeling was performed. Further data on prototype testing are now provided.

Methods:

An integrated fluidics portion of the prototype was designed, cast, and tested. A sensor was created using screen-printed sensors integrated with a silicone rubber fluidics system and absorbent polyurethane foam. A simulated eye surface was prepared using fluid-saturated poly(2-hydroxyethyl methacrylate) sheets, and the disposable prototype was tested for both reproducibility at 0, 200, and 400 μ*M* glucose ($n = 7$) and dynamic range of glucose detection from 0 to 1000 μ*M* glucose.

Results:

From the replicated runs, an established relative standard deviation of 15.8% was calculated at 200 μ*M* and a lower limit of detection was calculated at 43.4 μ*M*. A linear dynamic range was demonstrated from 0 to 1000 μ*M* with an R^2 of 99.56%. The previously developed model predicted a 14.9% variation. This compares to the observed variance of 15.8% measured at 200 μ*M* glucose.

Conclusion:

With the newly designed fluidics component, an integrated tear glucose prototype was assembled and tested. Testing of this integrated prototype demonstrated a satisfactory lower limit of detection for measuring glucose concentration in tears and was reproducible across a physiological sampling range. The next step in the device design process will be initial animal studies to evaluate the current prototype for factors such as eye irritation, ease of use, and correlation with blood glucose.

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Abbreviations: (BG) blood glucose, (GDH-FAD) glucose dehydrogenase with flavin adenine dinucleotide, (LLD) lower limit of detection, (PBS) phosphate-buffered saline, (PDMS) poly(dimethylsiloxane), (pHEMA) poly(2-hydroxyethyl methacrylate), (RSD) relative standard deviation, (SMBG) self-monitoring of blood glucose, (TG) tear glucose

Keywords: biosensor, diabetes mellitus, glucose monitoring, tear glucose monitoring

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