A wearable microneedle array sensor shows high correlation between dermal glucose and venous blood glucose

Samant, P.; Christiansen, M.; Bhavaraju, N.; Campbell, A.; Lal, R.; Sattayasamitsathit, S.; Tangney, J.; Windmiller, J.; Peyser, T.A.

1 Biolinq Inc., San Diego, CA
2 Diablo Clinical Research, Walnut Creek, CA
3 Stanford University School of Medicine, Stanford, CA

OBJECTIVE

Current continuous glucose monitors (CGM) measure glucose in the subcutaneous interstitial fluid (ISF). Previous ex vivo research with hypodermic needles has shown that glucose in the dermal ISF is highly correlated to venous glucose with little or no lag time. However, this methodology is not viable for continuous measurement. Thus, we have developed and tested a wearable microneedle array sensor for continuous in situ measurement of glucose in the dermal ISF. A dermal CGM could be applied without an introducer needle and without pain during application.

METHODS

In this study the microneedle array sensor was tested against venous glucose measured every 15 minutes from a YSI analyzer in 8 hour sessions over 2 days (phase 1) and 5-7 days (phase 2).

RESULTS

Five participants without diabetes and 10 participants with diabetes were recruited for phase 1 and 10 participants with diabetes were recruited for phase 2. A high degree of linear correlation ($R^2 \geq 0.90$) between the microneedle array measured dermal ISF glucose and venous glucose was observed. The figure shows the linear correlation and temporal profile for one microneedle array sensor over 8 hours.

CONCLUSIONS

A wearable microneedle array measuring dermal ISF glucose can accurately track glucose values. The study demonstrated early human feasibility of a CGM based on microneedle sensing of dermal ISF.