In vivo Evaluation of an Osmotic Pressure-based Implantable Glucose Sensor Technology

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Background

A novel implantable glucose affinity biosensor (Sencell, LifeCare, Norway) is currently under development, which is based on competitive and reversible binding of glucose and the polysaccharide dextrane to the glucose specific lectin concavalin A (ConA). The Sencell technology uses osmotic pressure differences arising between a reagent chamber (containing active fluid with ConA and dextrane) and a diffusion chamber (in direct contact with interstitial fluid) to determine interstitial glucose concentrations. Both compartments are separated by a nanoporous membrane permeable to glucose and water, but not to ConA or dextrane. A first study in pigs has initially demonstrated the capability of the technology to track interstitial glucose. It has also led to specific sensor modifications for signal noise reduction, e.g. the introduction of a second measurement chamber to measure mechanical pressure signals and deduct them from the signals. This device iteration was now evaluated in another animal experiment.

Methods

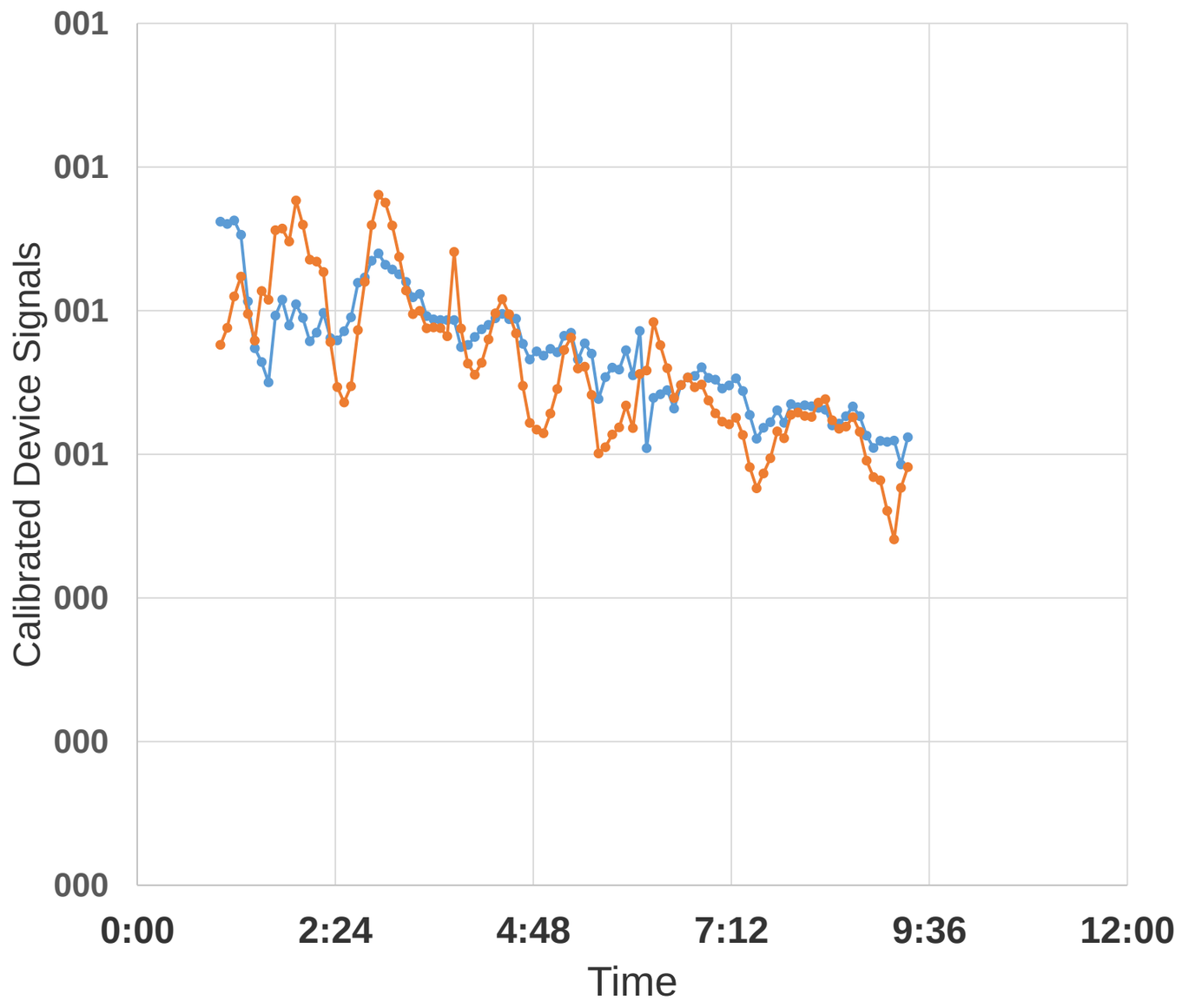
Implantation of four modified Sencell sensors and one Dexcom® G4 control sensor was performed in the back and the neck area of three pigs (1 female, 2 male), respectively (see Figure 1). After two days of equilibration and signal documentation, they received an i.v. glucose load of up to 100 mg/kg of dextrose. Reference measurements from capillary blood samples were performed using the YSI 2300 STAT Plus glucose analyser every 15 min for 5 h.

Results

Several Sencell prototype devices were able to track glucose changes paralleling the results of the Dexcom Sensor over extended time periods. In comparison to the previous results, deduction of movement artefacts as captured by the reference pressure chambers substantially reduced the noise level of the signals. The magnitude of the signals was in a predicted range and working sensors were matching G4 results (see Figure 2). Although the body temperatures in the animals within three experimental days partially exceeded 39°C, the activity of ConA was preserved. No external signs of inflammation were observed in the histology examinations.

Fig.1.: Osmotic pressure cell principle and experimental setup

Fig.2.: Raw signal of the Sencell device after retrospective one-point calibration with the Dexcom G4 sensor



Conclusion

Improved performance of the actual sensor after recent design modifications could be demonstrated *in vivo*.

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