In vitro Proof of Principle Experiment with the Osmotic Pressure-based Sencell Implantable Glucose Sensor Technology

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Background

Minimally invasive or implantable continuous glucose monitoring systems have become available and are increasingly adopted. A novel implantable glucose affinity biosensor (Sencell, LifeCare, Norway) is based on competitive and reversible binding of glucose and polysaccharide dextrane to the glucose specific lectin concavalin A (ConA). The Sencell technology uses osmotic pressure difference 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 chambers are separated by a nanoporous membrane permeable to glucose and water, but not to ConA or dextrane. Because the skin anatomy of pigs markedly resemble the human situation, we performed a first proof-of-principle experiment in this animal model using a wired device prototype.

Methods

Implantation of four Sencell sensors and one Dexcom® G4 control sensor was performed in the back and the neck area of three pigs (one female, two male), respectively. Subsequently, they received an oral glucose load of 75 to 150 g of dextrose. Reference measurements from capillary blood samples were performed using the YSI 2300 STAT Plus glucose analyzer every 15 min for 5 h. Statistical analysis tried to identify sensor patterns from the crude pilot sensor prototypes indicating the ability of the osmotic sensing technology to track interstitial glucose

Results

Several Sencell prototype devices were able to track glucose changes, especially when blood glucose levels exceeded 200 mg/dL. The magnitude of the signals was in a predicted range and working sensors were matching G4 results and displayed a lag phase of 20 minutes vs. plasma reference glucose. 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

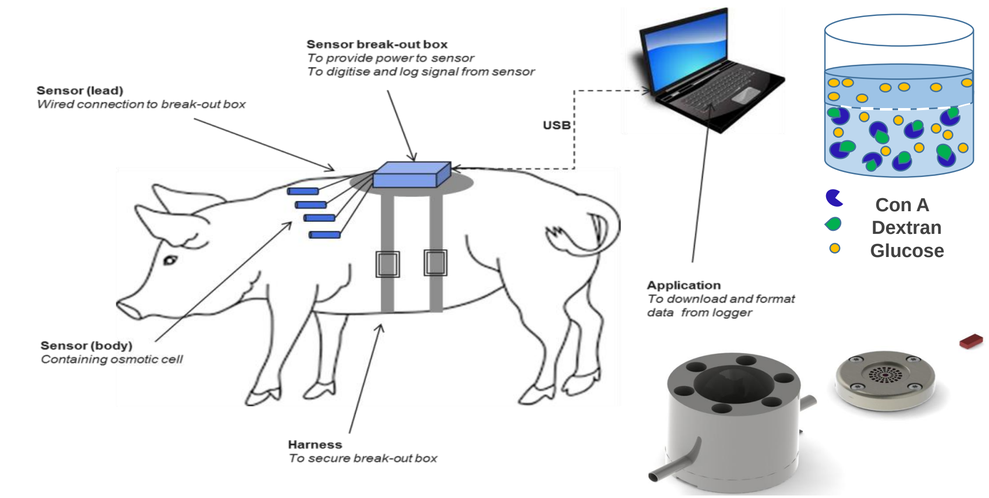
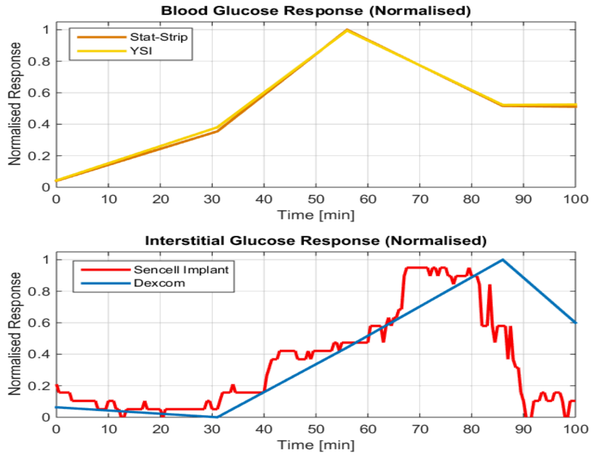
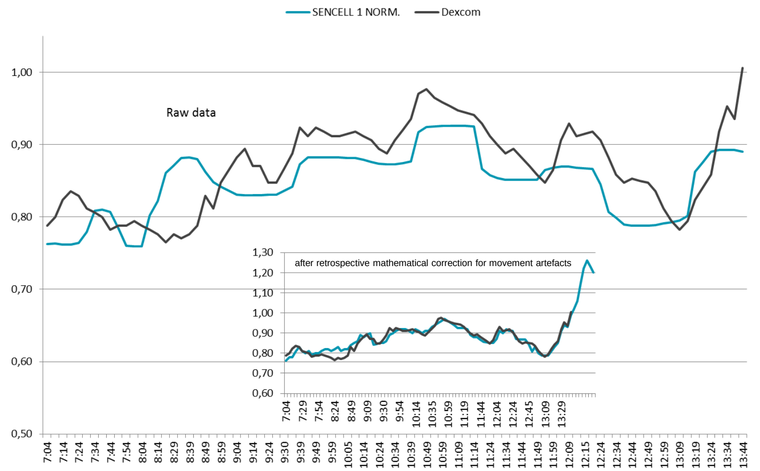


Fig.2.: Raw and retrospectively calibrated Sencell signals in comparison to the different reference methods





Conclusions

In conclusion, Sencell proof-of-principle has been demonstrated *in vivo*. Next development steps are now targeting to obtain a working prototype with more stable and predictable performance.

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