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Cystic Fibrosis Patient Monitor

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Introduction

Cystic Fibrosis (CF) is a genetic disease which affects the body's ability to regulate chloride movement across epithelial cells, leading to life-limiting conditions such as chronic airway infection and pancreatic disease. Treatments for CF are emerging which aim to correct and enhance the underlying CFTR protein dysfunction which causes the disease. Sweat Cl⁻ concentration is a key biomarker in gauging the efficacy of such treatments. To be able to measure Cl⁻ in sweat non-invasively in real time, we are developing a wearable, chloride-sensitive patch.

Methods

Pre-manufactured Ag/AgCl electrodes printed on a flexible polyethylene substrate were utilised for this study, consisting of a reference and working electrode. One of the electrodes was modified through the deposition of a pHEMA hydrogel film over the surface. The hydrogel was polymerised under a UV LED array and treated in a Cl⁻ saturated solution to produce a stable Cl⁻ reference electrode.

The device's sensitivity towards Cl⁻ ions was initially tested by observing the open circuit potential (OCP) developed between the pHEMA reference electrode and Ag/AgCl working electrode when exposed to KCl solutions of concentrations ranging from 1mM to 1M. This encompasses healthy physiological chloride concentrations and those seen in CF patients.

In vitro studies have also been conducted using a fluid-filled cell with a nano-porous membrane surface, designed to mimic the transdermal diffusion of ions.

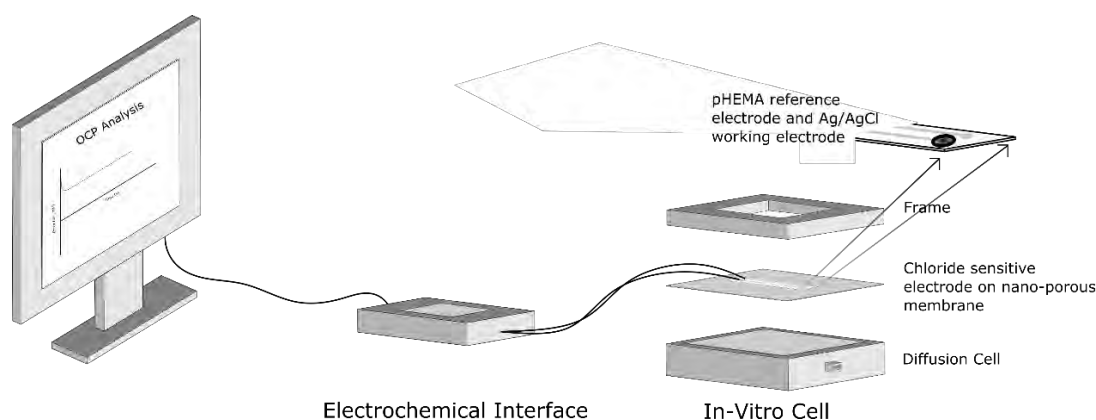


Figure 1. Experimental setup for *in vitro* skin model tests

Results & Discussion

An average sensitivity of 54 mV per decade (n=4) was found, indicating that the electrodes display a near-Nernstian response to the test solution concentration range. Tests undertaken with the *in vitro* skin model system have also shown that the device is sensitive to changes in chloride concentration made to the filling solution throughout the test period. These results indicate that the device is not only approaching the physical limit of sensitivity toward Cl⁻ concentrations within aqueous solutions, but that it has the capability of monitoring Cl⁻ levels via the diffusion of ions across a skin-like membrane.

Conclusion

This study shows that pHEMA-adapted electrodes can be used to successfully detect clinically relevant changes in Cl⁻ concentration. Studies carried out with an *in vitro* cell suggest that the electrodes could be used as part of a wearable device capable of monitoring transdermal chloride concentrations. Such a device would play a vital role in monitoring the impact emerging CF treatments have on CFTR functionality, the underlying cause of CF.

Acknowledgments

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