

Polymeric Microneedle-Based 'Dry' Electrodes for Wearable Cardiac Monitoring

Emma Baczkowski¹, Andrea Bocchino³, Mark O'Sullivan³, Conor O'Mahony³, Sabarna Mukhopadhyay², Neil Sutton², Sushrut Mehta², Sion Coulman¹ and James Birchall¹

¹School of Pharmacy and Pharmaceutical Sciences, Cardiff University, CF10 3NB

²SymConnect Ltd, Institute of Life Sciences 2, Swansea University, SA2 8PP

³Tyndall National Institute, University College Cork, T12 R5CP

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INTRODUCTION

- Electrocardiography (ECG):** clinical procedure used to record the electrical activity of the heart and aids in the diagnosis and monitoring of cardiovascular conditions e.g. Atrial Fibrillation¹.
- Signal acquisition: 'wet' electrodes applied to the surface of the skin where they transduce ionic potentials, generated by the heart, into electrical signals².
- 'Wet' electrodes use conductive gels to facilitate signal transduction but over time the gel dehydrates, reducing the quality of recorded signals in long-term patient monitoring².
- Microneedles (MN):** minimally-invasive devices which circumvent the stratum corneum and directly contact underlying epidermal layers which are considered more conductive². This negates the need for conductive gels and could improve the signal fidelity of ECG recordings.

AIM: to develop a suitable ex-vivo model whereby simulated cardiac signals are generated and acquired through ex-vivo skin.

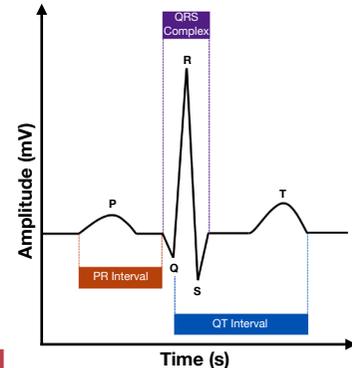


Figure 1: Labeled ECG waveform identifying P, Q, R, S and T waves. QRS complex, PR interval and QT interval are also highlighted.

METHODS

Clinical Electrocardiography

- Ethical approval**
Cardiff School of Pharmacy ethics committee
- Volunteer recruitment**
Ten volunteers (5 ♀ and 5 ♂)
- Inclusion criteria**
≥18 years with no KNOWN cardiac history
- ECG recording**
Three x 60 second ECG recordings
- Clinical review**
Data has potential health implications
- Signal processing**
Noise and artefact removal via MATLAB

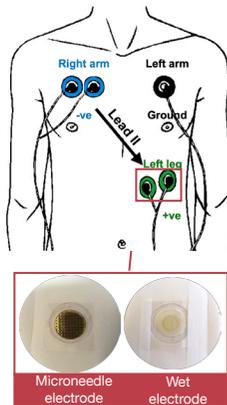


Figure 2: Placement of electrodes in a lead II configuration. Magnified images of MN electrode and a commercially available wet electrode.

Simulated Electrocardiography

- Cardiac waveforms emitted from a generator were scaled using a resistor divider and conducted through porcine skin pinned to compressed cork covered with conductive fabric. Wet, microneedle and blank electrodes, connected to a Cyton biosensing board, recorded signals.
- To account for signal losses, signals were recorded at multiple stages. Using MATLAB, signal-to-noise ratio (SNR) and correlation coefficients were calculated. Fast Fourier transform (FFT) was used to determine the magnitude of powerline noise.

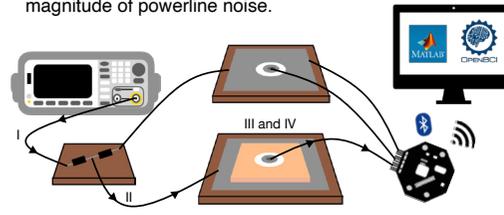


Figure 3: Diagrammatic representation of the ex-vivo model. Simulated signals were recorded directly from the generator (I), resistor divider (II), conductive fabric (III) and through porcine skin using wet, MN and blank electrodes (IV).

RESULTS

Microneedle-Electrodes

Table 1: physical features of solid, polymeric MN arrays. Data presented as the mean ±SD (n=9)

Material	Epoxy
Number of MNs per array	85 ±1.07
Length of MN (µm)	471.06 ±14.51
Tip interspacing (mm)	1.71 ±0.06
Base interspacing (mm)	1.20 ±0.04

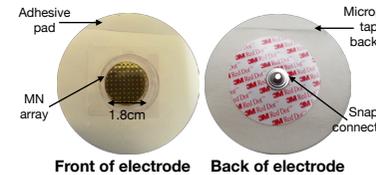


Figure 4: labeled stereomicroscope image of the front and back of a single-use, disposable MN-electrode.

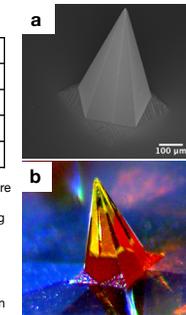


Figure 5: Uncoated, epoxy 500µm MN prior to insertion imaged with SEM (a) and light microscopy (b).

Clinical Electrocardiography

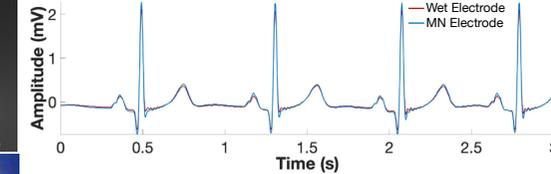


Figure 6: Part of an ECG trace simultaneously recorded with MN and wet electrodes from a 22 year old female volunteer at a gain of x24 using a biosensing board. Data detrended and filtered with a digital notch filter to remove 50Hz powerline interference.

- Powerline interference at 50Hz affected all traces.
- Variable MN puncture and/or poor retention within skin may have contributed to the amount of interference captured.
- Data captured from healthy volunteers helped optimise the heart rate and amplitude of the simulated cardiac waveform.

Waveform Optimisation and Simulated Electrocardiography

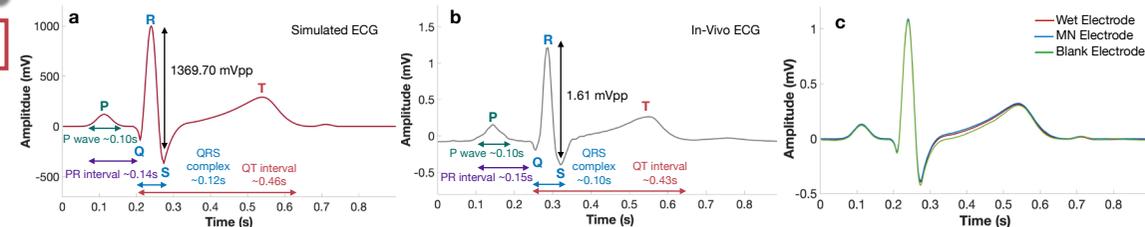


Figure 7: Comparison between simulated ECG (a) and an ECG recorded from a healthy volunteer (b). Simulated signals recorded from wet, MN and blank electrodes through excised porcine skin (c) as part of the study assessing signal loss. Data detrended and filtered to remove 50Hz powerline noise.

- Sample rate of 500Sa/s produced a heart rate of 66bpm which is within the range for a healthy, resting adult. Incorporation of a resistor divider allowed for signals to be scaled from V to mV to simulate the low voltages of real world cardiac signals.
- As signals travelled from the generator to wet, MN and blank electrodes, signal correlation and quality decreased as the level of noise increased. Upon removal of 50Hz powerline interference, signal correlation and quality improved for all stages.
- Similar performance by wet and MN electrodes, whilst blank electrodes were the most susceptible to noise.

CONCLUSIONS AND FUTURE WORK

Recording ECGs from healthy volunteers not only helped inform the development of our model, but importantly highlighted the promise and limitations of our current MN design. We are now testing an adapted electrode to improve MN retention in skin. Our ex-vivo model was capable of successfully generating and acquiring simulated signals through ex-vivo skin. This model is now being used to assess parameters which could affect MN-electrode performance.

1. Kligfield P et al. *J Am Coll Cardiol.* 2007;49:1109-27.2. Forvi E et al. *Sens Actuators A Phys.* 2012;180:177-86.