Trop-advisor

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Acknowledgements
Siu Kwan Cheng came up with the initial idea of troponin sensors and the application of personalised medicine. Wai Yiu Siu applied his knowledge in physics to guarantee the practicality of our device. Charmaine Lau utilised her illustration skills to design unique visual aids on our poster. Arvin Ian Ip and Yi Lam Kristy Li carried out extensive research and reached out to professionals for advice. As a team, we worked together meticulously to further develop ideas and bring them to life. Special thanks to Cheuk Hin Chau and Mr. Choudhary for answering our many questions based on their expertise on the subject.

Introduction

Myocardial infarction (MI) is a type of acute coronary syndrome (ACS) in which blood flow to the myocardium is restricted, causing cell death via a decreased oxygen supply to cardiac muscles. Common causes include the narrowing of coronary arteries by plaque formation and fatty streaks, as well as partial or complete blocking of coronary arteries by blood clots.

What is the problem?

There is an increasing number of patients with coronary heart disease both in the UK and globally that lead to MI among other conditions. Number of deaths where a heart attack was the underlying cause in England and Wales in 2021 is 20,061.

The NHS predicts in its long-term plan that numerous hospital admissions for heart attacks will occur in the next decade. This has already placed an increased burden on the A&E department, where the supply and demand for hospital beds are mismatched, increasing wait times. Putting pressure on the short staffed A&E department will cause the quality of care provided to be diminished.

BAME communities receive worse clinical outcomes than white patients when presenting MI, in particular during the COVID-19 pandemic. Thus, an innovative solution that can reduce inequalities and provide a preventive strategy for cardiovascular risks by early detection of ACS is necessary.

Comparison to existing solutions: Currently, troponin assays can only be carried out at the point of care, such as cardiology wards, with many cases not being dealt with fast enough. The 99th percentile, i.e. upper limit of normal (ULN) of troponin level based on healthy individuals, is used as a threshold for MI. This approach is non-personalised and can often lead to misdiagnosis.

Audience

Patients with a family history of heart attacks, recovering from MI, and diabetic patients have a higher chance of developing MI. Determination of whether a patient should be given this device will be further advised by consultants with regards to risk factors and comorbidities.

Proposed Solution

We designed a wearable wristband that consists of two microneedles containing "on-device" electrochemical troponin I and CK-MB sensors respectively, used to perform a minimally invasive assessment of these 2 biomarkers in the interstitial fluid at regular time intervals at home, to maximise the opportunities to improve care for patients with a high risk of MI.

How the Solution Works

A microneedle cartridge is attached onto the wristband, and measurements of troponin I and CK-MB are made at timed intervals advised by cardiologists. The microneedles are hollow, containing a sensing lobe.

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The operation of the microneedle is controlled by a solenoid. The microneedle is partially composed of soft iron and surrounded by a wire coil. The microneedle extends into or retracts from the epidermis depending on the presence of current in the electric circuit.

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10 μm of ISF can subsequently be exerted up to the sensing lobe by capillary action for detection by an electrochemical method.

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The collected data is sent to a mobile device, utilising the concepts of IOT and Body Sensor Networks (BSNs) for continuous monitoring as a personalised measurement of cardiovascular risk to improve prevention strategies.

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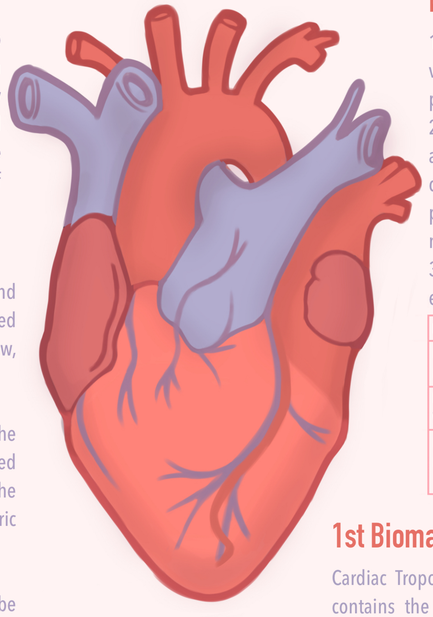
The microneedles remain in the epidermis for days, providing continuous monitoring of troponin levels. This feature is similar in principle to continuous glucose monitors, and is meant to address the disposable nature of most microneedle solutions. The change in troponin level over time can be monitored; if a large change in troponin level is detected, the consultant will be alerted and the patient is advised to seek immediate medical attention.

Why Microneedles?

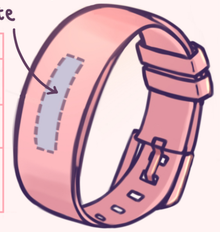
The needle is sharp enough to minimise nerve contact when penetrating through to the epidermis, hence it does not affect pain receptors in the dermis, providing a minimally invasive and painless way to detect biomarkers in the interstitial tissue fluid.



Key features of the solution

1. An evidence-based innovation that promotes equity in cardiac care in vulnerable populations and BAME communities, through measuring personalised cardiovascular risks of individual patients.
2. Early detection boosts 'out-of-hospital' care, providing timely responses and alerting patients to seek medical attention prior to onset of serious conditions. Differences in troponin levels allows more effective triage, prioritising more urgent cases and reducing the necessity of life-long medication like statins and beta blockers.
3. An intuitively designed wristband that does not require medical expertise to use.

Product specification	Description
Ergonomically Friendly	Designed according to anthropometric data with various sizes suiting people of all ages
Reusable and Waterproof	Designed for prolonged wearing and machine washable
Lithium Ion Rechargeable Battery	Powered by an energy efficient rechargeable battery that aligns with the principles of a green design



1st Biomarker Tested: Troponin

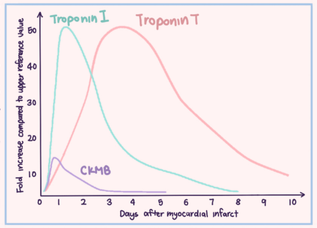
Cardiac Troponin, a type of calcium-regulatory protein found in heart muscle. It contains the subunits troponin I, used to inhibit actin-myosin interactions; and troponin T which regulates contraction. When heart muscles are damaged, troponin is released into the bloodstream and travels into the interstitial fluid by ultrafiltration.

Increased heart damage correlates to a greater amount of troponin released, exhibited in the graph; as cell necrosis increases, a greater amount of free cytoplasmic troponin is able to enter the bloodstream and hence the interstitial fluid. Transmural necrosis of the myocardium requires at least 2 hours, and the sensitivity of troponin increases with time.

Nonthrombotic causes of increased troponin levels involve a mismatch between the demand and supply of oxygen to the myocardium; release of myocardial depressive factors causes free troponin to degrade into smaller pieces with higher permeability, thus released more readily into systemic circulation.

2nd Biomarker Tested: CK-MB

CK-MB, an isozyme of creatine kinase that is specific to the heart, is used to catalyse the conversion of creatine phosphate to creatine. During myocardial reinfarction, CK-MB is used as a cardiac marker due to troponin T levels still remaining high in circulation for 10-14 days as the troponin complexes attach to other components of thin filaments in cardiomyocytes , thus making the change in troponin T undetectable.



Product Testing and Clinical Investigation

Prior to implementation, educating the public on MI and its associated risks is necessary for effective implementation, and can be achieved through product testing and trials. We aim to increase the public's understanding of heart diseases so positive feedback can be expected.

1. Pilot stage	2. Pivotal stage	3. Post-market stage
First, a prototype is tested for its ergonomics, and the design is finetuned. It is then tested on a small number of healthy volunteers to ensure interstitial fluid can be drawn with minimal harm. Volunteers are monitored closely and potential side effects are identified.	Tested on several hundreds with a family history of heart disease and those with high risks of MI, such as diabetics, to assess detection efficiency and accuracy, as well as its correlation to MI. The device is also submitted to bodies like the MHRA for approval.	Tested on thousands with varying ages, genders, and ethnicity and user surveys are conducted. Observe safety and efficacy over a long period of time, and biocompatibility is assessed by collecting results from people with different skin types.

Ethical Considerations in Clinical Investigation

Informed consent will be obtained from all volunteers after a thorough explanation of the sensor mechanism. Anonymity and confidentiality are maintained, with no harm being done to the volunteers. Test results will be clearly communicated to all volunteers. All volunteers have the right to withdraw during the testing period.

Feasibility in Commercial Production

Being a personalised clinical device that aligns with the NHS long-term plan, it has the potential to receive sufficient funding for continuous research, development, and mass production. Expected to be cost-effective as the foreseeable reduction in A&E expenses and manpower supersedes the cost of production, it will become increasingly affordable in coming years.

Limitations

The wristband utilises the concept of IOT and focuses on early detection of MI, with a high sensitivity and specificity. The use of microneedles may cause skin irritation and can impede articulation. Despite these minor setbacks, our product boasts minimal invasiveness, personalised and efficient detection, and high accessibility with innovations in miniaturisation.

References