NIHR | Trauma Management MedTech Co-operative

0011

CASE STUDY

SOFTCELL:

A REAL TIME CELLULAR PH MONITORING SYSTEM TO DIAGNOSE ACUTE COMPARTMENT SYNDROME

Softcell®

FOR FURTHER INFORMATION PLEASE CONTACT:

NIHR TRAUMA MIC

www.traumamic.nihr.ac.uk

traumamic@uhb.nhs.uk

SOFTCELL MEDICAL

softcellmedical.com

info@softcellmedical.com

+44 (0) 7977 916089

PROJECT SUMMARY

The NIHR Trauma Management MedTech Co-operative (NIHR Trauma MIC) collaborated with Softcell Medical Ltd, a UK-based medical device company, to undertake human factors validation testing on the Softcell pH monitor and probe system.

CLINICAL NEED

Acute compartment syndrome (ACS) is a post-trauma related complication which can cause severe tissue ischaemia, yet is very difficult to diagnose. The blood supply becomes restricted and oxygen cannot reach the tissues in the affected area, resulting in changes in the cell structure and function. In extreme cases, ACS can cause unnecessary amputation and loss of life.

These outcomes could be prevented with early diagnosis. However, the results from current detection methods (such as using a pressure probe) do not correlate well with underlying muscle or limb ischaemia.

THE SOLUTION

Softcell Medical have developed a real time cellular pH probe for monitoring tissue acid levels. As acids are created as by-products following ischaemia, the Softcell pH monitoring system therefore provides an accurate and reliable direct measure of the health of the tissue.

A pH probe is inserted into the tissue through a cannula and connects to the Softcell monitor, which records the pH levels. Up to four probes can be used simultaneously. Being able to detect ischaemia or diagnose ACS earlier will aid clinicians in deciding whether further interventions are needed after traumatic injury or surgery.

Fig 1: Softcell pH monitor and probe

HOW WE SUPPORTED

The NIHR Trauma MIC conducted human factors validation (formative usability) testing in the Medical Devices Testing and Evaluation Centre, to acquire feedback on the following points to gain recommendations for device development:

- ease of use of the device (e.g. method of probe insertion and interpreting the results provided by the monitor)
- training requirements and instructions for use for the probe and monitor
- checking the monitoring system

The NIHR Trauma MIC supported by:

- Recruiting nine healthcare professionals with a background in trauma to participate in the study
- Planning, setting up and moderating the study (following training from the company, participants tested the device on a simulated patient in a realistic but simulated environment)
- Filming the testing sessions using a static, high-definition camera
- Conducting a post-study questionnaire and interview
- Compiling a comprehensive formative usability test report for Softcell Medical, plus an edited video of the training and usability testing sessions

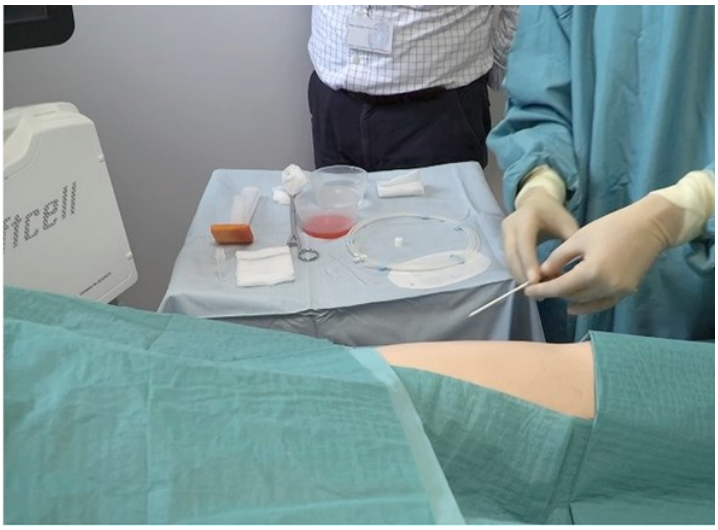

Fig 2: Set up of simulated patient for the insertion of the probe into an I.M. injection pad

OUTCOME

The one day formative study confirmed a high level of interest in the concept of the tissue pH monitor. The system was straightforward to use and the study has provided some suggestions for improving the device which the company will incorporate into subsequent device developments. It has also assisted with regulatory approvals to obtain a CE mark.

Following the success of the formative usability study, Softcell Medical are currently planning a summative usability study (the next stage in the device development process) in collaboration with the NIHR Trauma MIC.

The upcoming summative three day study will provide feedback on the device for quality assurance and in accordance with ISO62366. The independent report generated will be suitable for the Product Technical file and FDA approval.