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CASE STUDY

CEREBROTECH™ VISOR

REAL-TIME
ASSESSMENT OF
BRAIN INJURY TO
PROVIDE
ADDITIONAL
INFORMATION AND
FACILITATE EARLY
INTERVENTION



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PROJECT SUMMARY

The NIHR Trauma Management MedTech Co-operative (NIHR Trauma MIC) has collaborated with Cerebrotech Medical Systems in the evaluation of the Cerebrotech Visor, a non-invasive device consisting of a scanner, console and disposables. The device uses Volumetric Impedance Phase-shift Spectroscopy (VIPS™) technology which provides real-time assessment of the brain's status following strokes and other brain injury, potentially facilitating earlier intervention. Changes in the brain's fluids, such as those involved in stroke, bleeding, or oedema, can be detected by monitoring fluctuations in intracranial electrical properties, called bioimpedance. These changes are detected by measuring the alterations in low-power (less than that of a mobile phone) radio waves generated by the device as they pass through the head.

CLINICAL NEED

According to NICE Clinical Guideline 176 (2014):

Head injury is the commonest cause of death and disability in people aged 1–40 years in the UK. Each year, 1.4 million people attend emergency departments in England and Wales with a recent head injury. Annually, about 200,000 people are admitted to hospital with head injury, of these, one-fifth have features suggesting skull fracture or have evidence of brain damage.

Emergency departments see a large number of patients with minor or mild brain injuries such as stroke, and need to rapidly identify the small percentage of people who may have or will go on to develop serious acute intracranial pathologies. Providing a fast, non-invasive method of detecting complications in these patients could greatly improve the efficiency of treatment for head injury.

THE SOLUTION

Cerebrotech Visor, utilizing VIPS, is a bioimpedance spectroscopy device that non-invasively detects changes in intracranial fluids. It is indicated for patients who are at risk for cerebral oedema and is intended as an aid to physiologic assessment in conjunction with clinical judgment and current standards of care. In addition, the Visor non-invasively detects bioimpedance asymmetry, including asymmetry associated with large acute ischemic stroke in patients who are being evaluated for acute stroke.

Because the Visor is robust, portable, and non-invasive, it can be used as a valuable adjunctive clinical monitoring

instrument in a variety of settings

HOW WE SUPPORTED

- Provided advice pertaining to the introduction of the Visor into European markets, and associated product beta testing
- Supported applications for grant funding
- Undertook a feasibility study in healthy volunteers to determine how changes in head position alter the device readings
- Orchestrated a usability study to assess how nursing and clinical staff experienced fitting the device onto a simulated patient

Additionally, we facilitated a study, in collaboration with Coventry University, to investigate the usability of the device with 16 paramedics (consisting of lecturers and second year paramedic students) within Coventry University's Science and Health Building's ambulance simulator facility. Assistance provided encompassed:

- Usability testing strategy and plan: formative (observational) study
- Evaluation and risk assessment of the user interface (UI)
- Recruitment of representative test participants
- Relevant documentation preparation e.g. consent forms
- Effective moderation of the usability test
- Data management, analysis, and UI recommendations

The results of the usability work have led to valuable feedback, and ongoing improvements being implemented into the device.

The device is CE marked and cleared by the U.S. Food and Drug Administration.

REFERENCES

National Institute for Health and Clinical Excellence (2014) Head injury: assessment and early management. NICE guideline (CG176)