FREMS Neurovascular Rehabilitation: effective innovation for the treatment of peripheral neurovascular complications (#2076)

(Submitted by Bharat Vadukul | 21/07/2016 - 10:15 | Detailed Submission)

Innovation \`Elevator Pitch\'

The FREMS Solution is an effective means of combating neuropathic pain in diabetics with clinical trials showing the benefit persists at the 4 month follow up. For chronic ulcers FREMS restores perilesional perfusion and rapidly reduces pain.

Overview of Innovation

FREMS is the result of research dedicated to realise a non pharmacologic system able to treat vascular and neurological diseases such as diabetic neuropathy.

FREMS is a new-generation biocompatible electrical neurostimulation. The healing effects of FREMS occur through a direct and indirect action on the biological control systems and especially in the autonomic system.

FREMS works thanks to a series of two-phase, asymmetrical and electrically balanced electrical pulses: a ‘simultaneous modulation’ of pulse Frequency, Amplitude and Duration. FREMS is an innovative, proven and easy-to-apply treatment method against pain.

FREMS is delivered via Aptiva and Satellite medical devices with dedicated transcutaneous electrodes for clean and simple application without side effects. The treatment involves a series of 30 minute daily sessions over a few weeks that can be performed both at hospital or at home.

As demonstrated by studies performed in recent years, FREMS delivers pulse sequences that can significantly increase the release of plasmatic growth factors. The analysis of systemic blood samples in diabetics and non-diabetics, taken before, during and after FREMS neurostimulation, has shown increases in the levels of VEGF and other angiogenetic growth factors.

For painful chronic leg ulcers FREMS significantly promotes epithelisation and decreases pain levels after as little as 36-48h with no side-effects. It has long-lasting effects which can be seen 2 months after the end of treatment and significant accelerates healing times.

For various etiologies of chronic leg ulcers FREMS can be a valid method of healing chronic cutaneous ulcers with significant reductions in area and depth a few weeks after commencing FREMS. The treatment increases the quality of assistance and the quality of life of the patient.

For painful Diabetic neuropathies FREMS provides safe and effective treatment for neuropathic pain in diabetics and can modify some functionality parameters of the peripheral nerves such as an increase in tactile sensorial perception and in the speed of conduction of the motor nerve. The clinical effects persist at the 4 month follow-up.

For arteriopathy FREMS has significant effects on diabetics with PAD; increase in oxymetric values at the 3-month follow-up; increase in walking distance free of pain at the 3 month follow up; improvement in the characteristic parameters of the endothelial system.

Stage of Development

Market ready and adopted - Fully proven, commercially deployable, market ready and already adopted in some areas (in a different region or sector)

WMAHSN priorities and themes addressed

Long term conditions: a whole system, person-centred approach / Wellness and prevention of illness

Online Discussion Rating - 4 (votes 1)

Initial Review Rating - 5 (votes 2)

Compelling proposition - 5
Innovation fit - 5
Health outcome potential for the region - 5
Wealth creation opportunity for WM region - 5
Innovation stage - 5

Benefit to NHS
The most comprehensive analysis to date concludes that the cost of diabetes to the NHS is £9.8bn in direct costs in 2010/11. Around 80% is spent on complications. (Hex et al. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. Diabetic Medicine (2012). Available at: http://onlinelibrary.wiley.com/doi/10.1111/j.1464-5491.2012.03698.x/abstract)

People with diabetes are more likely to be admitted to hospital than people without the condition. In 2009-10 there were 160,000 more admissions for people with diabetes than would be expected for people of the same age without the condition.

They have longer hospital stays and are more often admitted overnight for planned procedures that could be performed as day cases. There were:
- 570,000 extra bed days for people with diabetes
- 40,000 more overnight admissions that would be performed as day cases in people without diabetes.

Annual inpatient care, to treat short and long term complications of diabetes, is estimated at between £1,800 and £2,500 per patient. This compares with annual outpatient costs, which includes the cost of medications and monitoring supplies, estimated at between £300 and £370 per patient. (http://www.diabetes.co.uk/cost-of-diabetes.html)

The following annual costs result from diabetes:
- Cost of absenteeism: £8.4 billion per year
- Cost of early retirement: £6.9 billion per year
- Cost of social benefits: £0.152 billion

People with diabetes are at increased risk of peripheral arterial disease and neuropathy, as well as having a higher risk of developing infections and decreased ability to clear infections. Therefore, people with diabetes are prone to frequent and often severe foot problems and a relatively high risk of infection, gangrene and amputation.


Early detection and effective management of diabetic foot ulcers can reduce complications including preventable amputations, improving patient outcomes and reducing cost to the NHS.

Benefit to WM population
Diabetes has huge implications for quality of life and life expectancy, with costs to the NHS and to the economy.

The West Midlands has a considerable healthcare problem due to diabetes. 8.1% of the West Midlands' adult population has diabetes, higher than the English average, with the figure predicted to rise.

There are 346,339 registered patients with diabetes out of a reported population of 4.76 million. The prevalence is therefore 7.28%, whilst nationally the England prevalence is high but only 6.37%. Of concern is the fact that the rate of increase in the prevalence of diabetes over the last 3 years was 34.9% higher than in England as a whole. (NHS England (West Midlands) http://www.wmscnenenate.nhs.uk/files/7914/6169/3440/Diabetes_Service_Specification_Final_April16.pdf)

The FREMS Solution is an effective innovation against pain and functional recovery that can increase quality of life for patients and reduce the burden on health services, thus reducing cost to the NHS, and increasing economic productivity.

Current and planned activity
BHR is looking for the following with respect to their involvement with WMAHSN:

1. Creating awareness of the FREMS system both within the west midlands and the wider NHS arena
2. To help identify interested diabetes centres who can utilise the FREMs for their patients
3. To provide a platform for application for grant funding for further research into the use of the FREMS Aptiva system
4. To support an application of an HTA assessment by NICE
5. To provide support to BHR in gaining access to the health networks that have an interest in new and novel technologies

BHR is hoping to start an evaluation of the FREMS Aptiva at the Endocrinology and Diabetes Centre at the Birmingham Heartlands Hospital subject to committee approval to show the utility of the FREMS Aptiva system.

**What is the intellectual property status of your innovation?**

The FREMS IP is covered by worldwide patent.

**Return on Investment (£ Value)**

medium

**Return on Investment (Timescale)**

3 years +

**Ease of scalability**

3

**Detailed submission**

**Regional Scalability**

Please describe how the innovation could be scaled across the WM region. Have you implemented at scale in any other regions?

**Measurement of outcomes**

**Measures**

What outcomes are you hoping to achieve and what are the measures that you will use to gauge the success of the innovation and how will these assessments be made? Please ensure that you have quality, safety, cost and people measures.

**User Comments**