Functional Electrical Stimulation

WORK PACKAGE - 10

Finetech Medical Ltd. (FTM)
Salisbury District Hospital (SDH)
University of Salford (USAL)
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What is FES

• FES is a way to produce useful movement from paralysed muscles.
• Electrical impulses are applied, causing the muscle to contract in a controlled way.
• FES can be used to assist standing, bladder function, walking and hand function.
• Spinal cord injury, Stroke, Multiple Sclerosis, Cerebral Palsy & Parkinson Disease.
What is FES

- Movement in unaffected people starts from the central nervous system (CNS).
- Signals pass into the peripheral nervous system (PNS).
- The nerves of the PNS deliver the signal to the motor point of the muscle.
What is FES

Action Potentials progress along the nerve by jumping between the uninsulated Nodes.

- Nerve Bundle
- Schwann Cell
- Myelin Sheath
- Axon
- Depolarised Region (node of Ranvier)
- Epineurium
What is FES

- FES requires the PNS to be intact.
- FES induces electrical impulses in the stimulated nerve that evokes action potentials to ‘replace’ the signal that would have come from the CNS.
The two sides of the story

OUTSIDE - Surface electrodes
100V, 100mA, 40Hz, 350us pulsewidth

[Diagram showing active and indifferent electrodes and electromagnetic field]
The two sides of the story

INSIDE - Implanted electrodes
10V, 2 - 20mA, 40Hz, 350us pulsewidth

Electrode pair placed close to the nerve

Electromagnetic field

Evoked Action Potentials

Epineurium
Who are FTM, SDH & USAL

FineTech Medical Ltd has a 20 year history of specialist manufacturer of implantable medical devices.
Who are FTM, SDH & USAL

- Class 100,000 assembly and test clean room.
- Integrated contract sterilisation service and microbiological support.
- CE Marking of devices through Notified Body.
- From initial concept through to prototyping and final production.
- BS EN ISO 13485:2003 and FDA (QSR)
Who are FTM, SDH & USAL

The FineTech Brindley Bladder Control System
The Bladder System (VOCARE)
Eliminates urethral catheters
Decreases wetness
Decreases urinary tract infections
Restores control

The FineTech Dropped Foot System
STIMuSTEP™
For the treatment of dropped foot, a chronic condition characterised by the inability to raise the foot during the swing phase of walking. The system has two stimulation channels, this allows for correction of dorsiflexion (foot lift) and eversion (ankle turn-out).

Surgical Stimulator
Generates stimulation for delivery through Surgical Probes to nerve tissues.
Who are FTM, SDH & USAL

- The Medical Physics department at Salisbury Hospital has over 20 years experience of bringing both surface and implantable FES into clinical use.
- The department is made up from a mix of clinicians, engineers and scientists.
<table>
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<th><strong>Who are FTM, SDH &amp; USAL</strong></th>
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**Salisbury District Hospital**

**ODFS**
Odstock Dropped Foot System
A single channel surface FES system for restoring gait. The system automatically adapts to walking speed.

**MS2**
Two channel, clinical exercise stimulator with selectable programmes.

**O2CHS**
A two channel stimulator for functional use, accepts external triggers.

**O4CHS**
A four channel stimulator for exercise and functional use. Finds applications in cycling and rowing.
Who are FTM, SDH & USAL

- Measuring human movement.
- Identifying predictable patterns of movement.
- Developing algorithms to control FES stimulation for the upper limb.
Developing the upper limb application

- **Develop clinical protocols**
  - Selection criteria
  - Pre – implant treatment plan
  - Post – implant treatment plan

- **Design and build equipment**
  - Develop surface and implant stimulators
  - Use common software for both devices

- **Develop a control methodology**
  - Use of available sensor outputs to drive FES

- **Patient trials**
  - Test surface system on stroke patients
  - Refine control technique
  - Validate software
Developing the upper limb application

• Clinical Protocol
  – Patients will require active arm movement and the ability to grip. The FES will provide support to the wrist and enable the hand to release from a grip.
  – A six months period using surface FES will be required prior to implant.
  – Patients will be followed up post implant, initially very frequently and then twice yearly.
Developing the upper limb application

• Design and build equipment
  – Surface system
    • Test software and control methodology for implant
    • Required as CE marked device for pre-implant treatment
  – Implant system
    • The implanted receiver – stimulator
    • The external controller
Developing the upper limb application

• Control methodology
  – Initial techniques used by Salisbury
    • Simple conditioning of multi-axis accelerometer signals
    • Refined during patient trials
  – Method being developed by Salford
    • Complex interpretation of multi-axis accelerometer outputs to identify and predict desired movement patterns.
    • Integrate subsequent algorithms with control of the FES stimulation
    • Development of a ‘virtual sensor’ tool to assist the patient set up process.
Developing the upper limb application

• Patient trials
  – Surface systems
    • Develop equipment and refine control techniques that will be directly applied to the control of the implant system
    • Test control software prior to implant
  – Implant system
    • Subset of the surface trial patients
    • Refine control of system
Developing the upper limb application

Ch1. Wrist extensors
Ch2. Hand extensors

Pulse width

Time

Trigger 1 Trigger 2 Trigger 3 Trigger 4
Developing the upper limb application

Channel 1 – Adjacent to the motor points of extensor carpi radialis longus/brevis (wrist extension)

Channel 2 – Adjacent to the posterior interosseous nerve (Finger extension, thumb extension and abduction)
Results to date

• Trial work so far
  – Pilot study with 2 subjects
  – Trial with 6 volunteers, system used at home with regular assessment visits to the department.
    • 3 male, 3 female
    • Average age 54 years (34 – 65)
    • Average time since stroke 4.5 years (2 – 9)
    • Side affected 3R 3L
    • 2 people affected on dominant side (1 male, 1 female)
    • 3 previous users of FES

  – All patients are using the system with triggered routines as well as for exercise.
Results to date

The patient in the picture is able to hold items but finds releasing them very difficult.

Using the system she is able to open her hand to pick items up, and again to release them – triggered by raising her arm.

One immediate benefit was the ability to use door handles.
Results to date

The patient in the picture is unable to open her hand.

Using the system this patient is able to open her hand to hold small items – triggered by raising her arm.

The biggest benefit she reports is being able to manicure her nails.
Results to date

The patient in the picture has three work related activities he wanted to achieve.

Using the system this patient is able to open his hand to hold a telephone – triggered by raising his arm.

Use a complicated door handle that requires both hands – triggered by rotating his arm.

Is able to open his affected hand to hold small objects.
Planned activity

• Complete the trial work with the 2 channel surface device.
• Carry out the implanted two channel trials.
• Using the knowledge gained from the 2 channel system, develop and trial a 6 channel surface stimulator that integrates with the Body Area Network.
• Build a working prototype of the 6 channel implantable system.
Planned activity

![Diagram showing a Planned activity setup involving a Motion Sensor, Controller, and Implant.](image-url)