Experience of Supporting Independence Through the Use of FES

Ian Swain

National Clinical FES Centre
Clinical Science and Engineering
Salisbury District Hospital, U.K.
Smart Engineering Research Group, Bournemouth University, U.K.
Suitable patients for FES

- **Definitely works**
  - Damage/ injury to CNS
    - Stroke, MS, CP, TBI, SCI,
- **Possibly works**
  - Dyskinesia
    - PD, ataxia etc, (we don’t know enough yet)
- **Does not work**
  - LMN
    - PID, peripheral nerve injury, polio, MND
Demand

- 140,000 new strokes per year in UK,
  - 10,000 under 50
  - 1,000 under 30
- 80% survival, 30% complete recovery
- about 10,000 left with dropped foot
- 85,000 MS in UK
- CP
- Head injury
- Incomplete Spinal cord injury
Evidence - Randomised Controlled Trial of the Odstock Dropped Foot Stimulator

Jane Burridge, Paul Taylor, Ian Swain
Salisbury District Hospital
Conclusions

- Significant increase in walking speed in FES group - no change in control group
- Significant fall in PCI in FES group - no change in the control group
- Reduction in spasticity in FES group only
- Reduced HAD score
- Positive cost-benefit (QALY gain of 0.042)
MS Trial

- RCT - FES c.f. Physio in 2nd Prog MS
- Both effective, in particular core stability exercises
- FES reduced number of falls
- New trial just completed to look at FES and physio combined
- Both trials funded by MS Trust
Patient with SLE, and subsequent bilateral CVA
Changes in Walking Speed

Fig. 2 Median % change in walking speed for MS (n=42) and CVA (n=116)
Initial walking speed MS 0.68ms\(^{-1}\) and CVA 0.57ms\(^{-1}\)
Changes in PCI

Fig 3 Median % change in PCI MS (n=42) and CVA (n=116)
Initial PCI MS 0.56 Heartbeats/min, CVA 0.57 Heartbeats/min
Reliable equipment

- MUST meet patients needs
  - User involvement essential to design process
  - large numbers needed to trial, then modify design accordingly, iterative process
- RELIABLE
  - ODFS footswitch works every time, fifteen years development $\sim 1$-200,000 cycles, $\sim \frac{6}{12}$ use
- Safe, and built to recognised standards
- Quality control, e.g. ISO 9000, FDA
- CE marked and approved in USA
Equipment Currently Available

- Few practical systems available
  - Surface - ODFS etc, WalkAid, Bioness H200 & L300
  - Implant - STIMuSTEP, FreeHand, Vocair (Brindley Bladder Stimulator), ActiGait

- From Salisbury we can supply (to registered users)
  - ODFS
  - 2 channel ODFS
  - 2 and 4 channel exercise stimulators
  - consumables
  - implanted dropped foot system - STIM-U-STEP
Stim-U-Step

- 2 channel implanted stimulator
  - CE marked, clinical service later this year

- Deep branch
  - dorsiflexion + inversion

- Superficial branch
  - dorsiflexion + eversion

- Developed with EU funding with, Salford, Het Roessingh and Finetech
Stim-U-Step - implanted peroneal nerve stimulator
Stim-U-Step
Staff Training

- FES equipment has a tendency to be sold from back pages of newspapers
- FES is not a treatment in itself it is a part of a rehabilitation programme
  - use with BoTox, orthotics, therapy etc
- Only trained staff can order and fit equipment.
- Therefore continuous training, education and support needed
Patient Support

- Clinical guidelines/ Care pathways
  - 82% success at initial assessment
- Prompt repair service
- Ongoing support for staff and patients
  - 86% compliance at 1 year
- Audit and regular questionnaires
- Feedback leading to new designs
Referral Criteria

- UMN problem
- Able to transfer independently (sit-stand)
- Able to walk 10m unaided
- The following can cause problems
  - Uncontrolled epilepsy
  - Pacemaker
  - Very high levels of tone, i.e. rigid
  - Diabetes
  - Unable to understand (carer included)
  - Odema/ obesity/ excessively dry skin
Clinical Service

- Dropped foot correction
- Bilateral dropped foot
- More complex movement problems
  - 2 channel stimulator
  - in conjunction with orthotics / Botox
- Upper limb function
- Facial stimulation
- Orthopaedic, TKA completed, THR?
Clinical Service 2

- In Salisbury -
  - up to 8 new patients per week
  - 49 follow up sessions per week
  - 1468 ODFS users, 331 2 Channel, over 250 upper limb & over 350 lower limb exercise

- Patients can pay privately, ‘self fund’ if their PCT will not, can transfer to NHS if funds become available
Clinical Service 3

- Set up:
  - 2 consecutive days
  - each session 1 to 1 \(\frac{1}{2}\) hours
- Follow up 6 weeks later
- Then 3 months later
- Then 6 months later
- Then yearly for as long as the system is used.
Clinical Service 4

- ISO 9000 and FDA systems in place
- Rapid assistance if experiencing problems
- Rapid repair service
- Telephone advice
- User questionnaire/ comment book
Conclusions to date 29/4/08

- In Salisbury we have seen over 2500 patients
  - over fourteen years longest usage
  - results improve most in the first $4\frac{1}{2}$ months but can continue to improve for much longer
  - estimated UK prevalence 100,000 incidence 8,000

- ODFS recognised by DEC and RCP and RSCG
- over 140 courses run, over 1500 staff trained
- Equipment, ISO 9000, CE/ FDA marking
  - 4280 ODFS stimulators sold to 175 centres to date
- 1st NHS commercial out company in England
  ‘Odstock Medical’
The Future

- In 2008
  - ODFS - Pace
  - Upper Limb - Duo Reach

- In 2009
  - ODFS - Pace MiWi
  - 2 Channel walking - Duo Pace
  - 2 Channel walking - Duo Pace MiWi
  - 6 Channel exercise stimulator

- 2010 onwards
  - A range of stimulators that talk to each other controlled by a small remote control.
ODFSIII - Patient Feedback

- Too big
- Battery difficult to insert / remove
- “Don’t like the wires”
- Difficult to attach to body
ODFS - Clinician Desirables

- Easy to set up
- More features
- Exercise mode
- Data logging
- Therapy / rehab functions
ODFS Pace - Main Features

- Smaller
Pilot trial of the 2 channel programmable stimulator for hand opening and reaching following stroke

Stimulation
•Wrist, finger and thumb extensors
•Triceps

Stimulation triggered by movement sensor
•Assistance to reach and open the hand in response to attempt to make movement

Funded by The Stroke Association
Accelerometer triggered hand stimulator

Action Research Arm Test (ARAT) (max. possible score 57)
Hand Stimulation 2

Canadian Occupational Performance Measure (COPM) - performance (p) & satisfaction (s) scores
ODFS - PaceMiWi
Main Features

- Wireless
- foot-switch

[Diagram of a walking person with wireless foot-switch highlighted]
ODFS - Pace MiWi
Main Features

- Wireless remote control
ODFS Duo Pace MiWi
Main Features

- Wireless
- future
Longer term future