

# **Experience of Supporting Independence Through the Use of FES**

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# 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**

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# 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

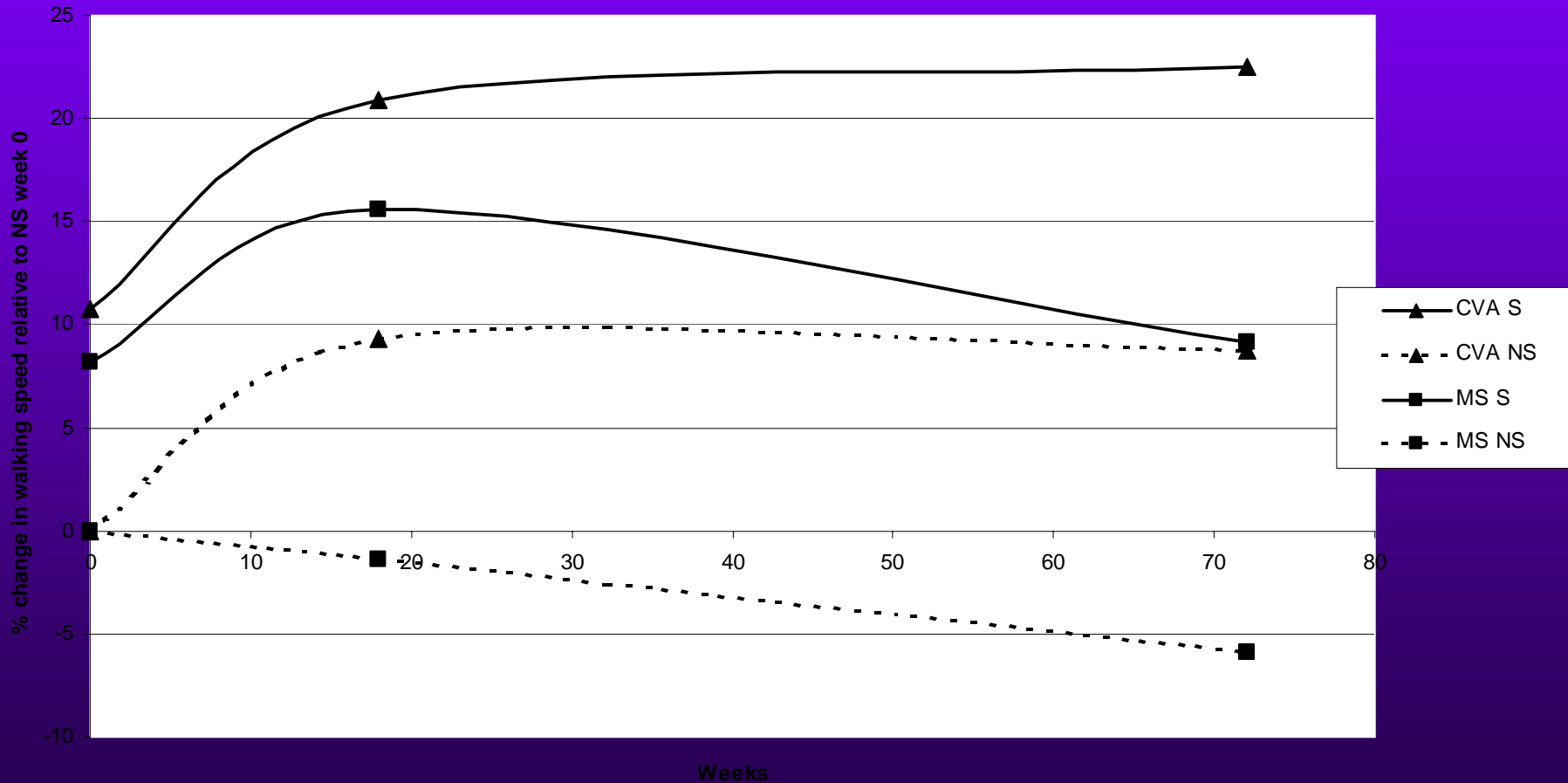


**Patient with SLE,  
and subsequent  
bilateral CVA**



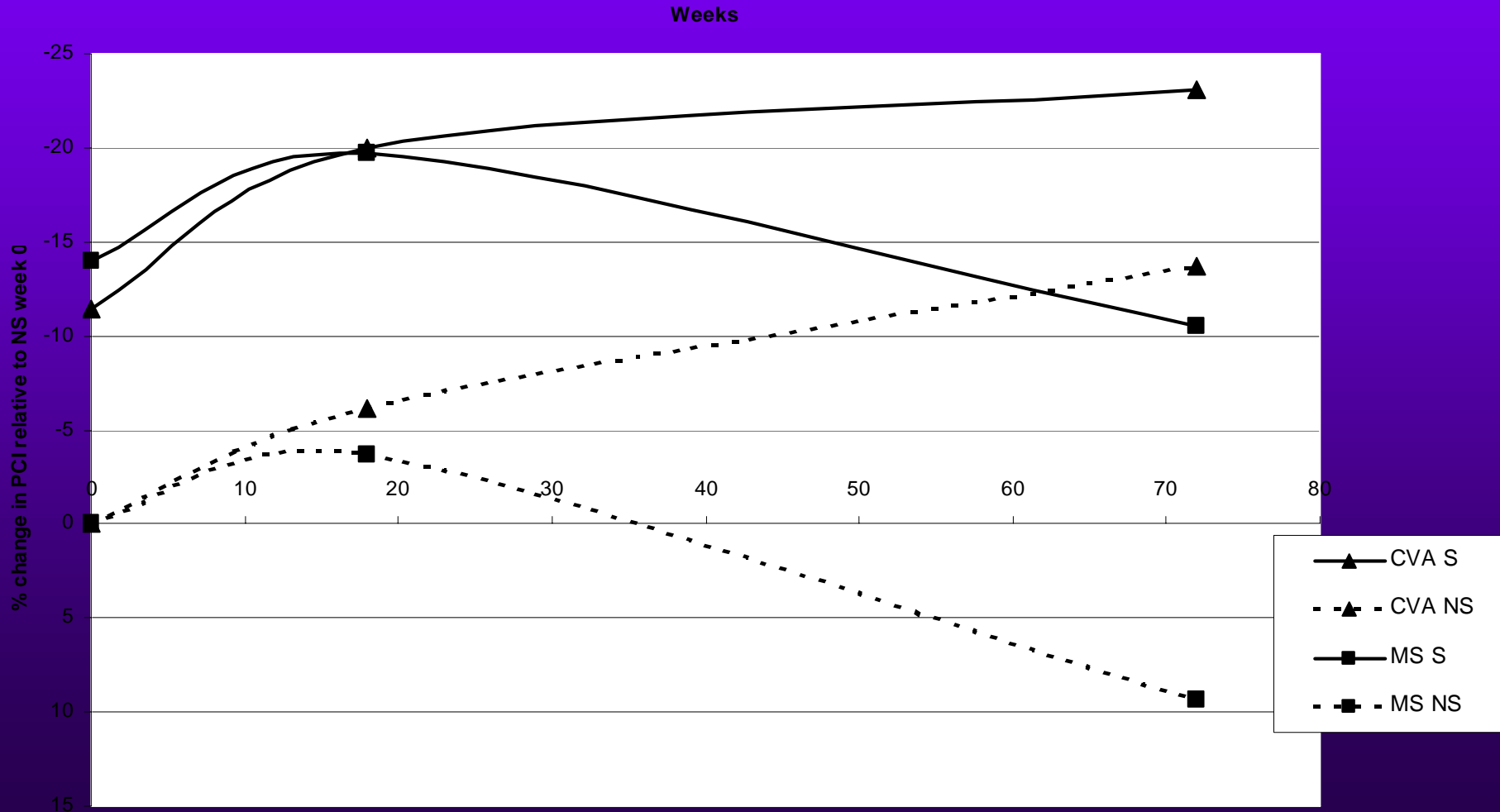
# Changes in Walking Speed

Fig. 2 Median % change in walking speed for MS (n=42) and CVA (n=116)  
Initial walking speed MS 0.68ms<sup>-1</sup> and CVA 0.57ms<sup>-1</sup>



# Changes in PCI

Fig 3 Median % change in PCI MS (n=42) and CVA (n=116)  
Initial PCI MS 0.56 Heartbeats/min, CVA 0.57Heartbeats/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,  $\sim^6/_{12}$  use
- Safe, and built to recognised standards
- Quality control, e.g. ISO 9000, FDA
- CE marked and approved in USA

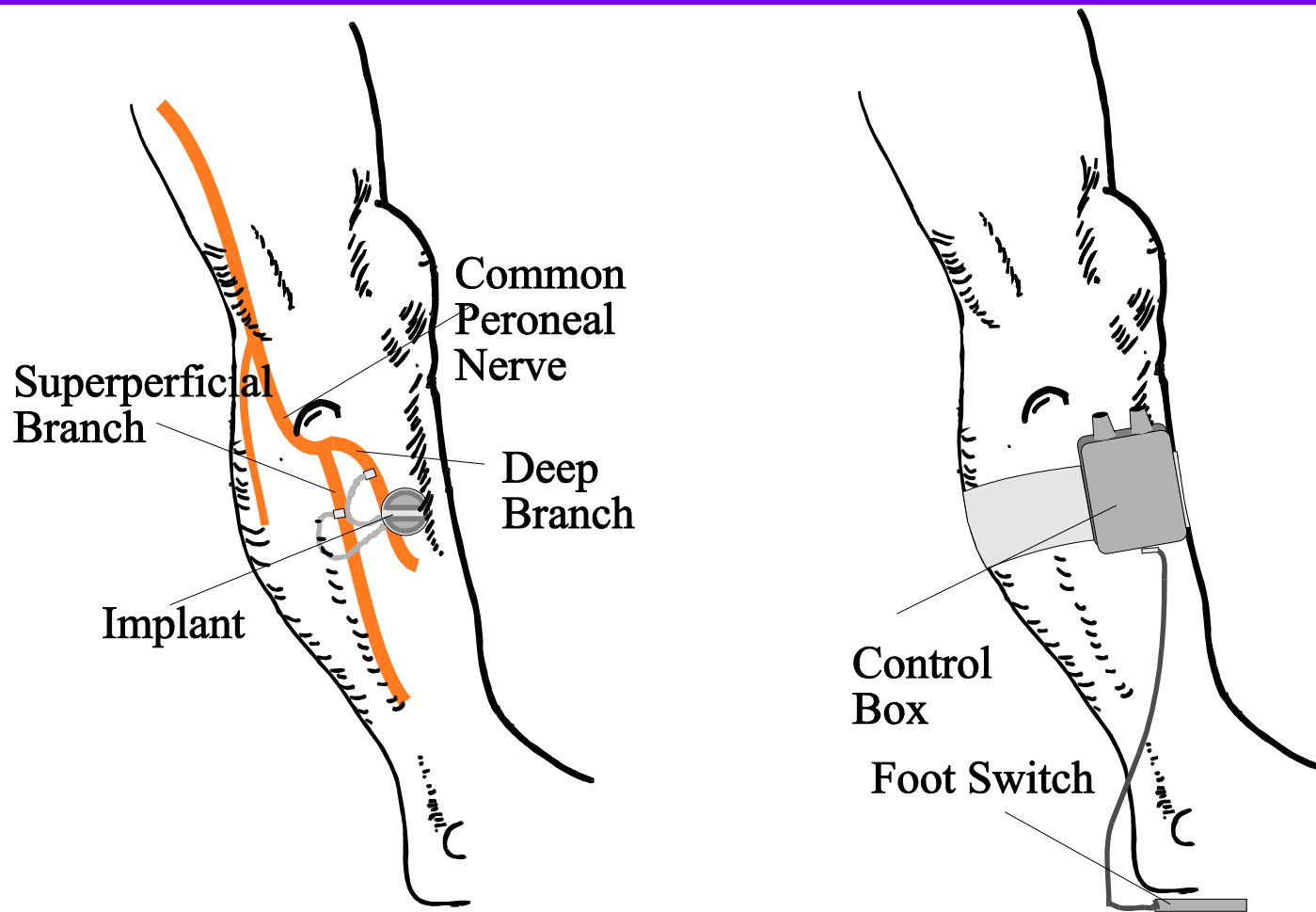
# Equipment Currently Available

- 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

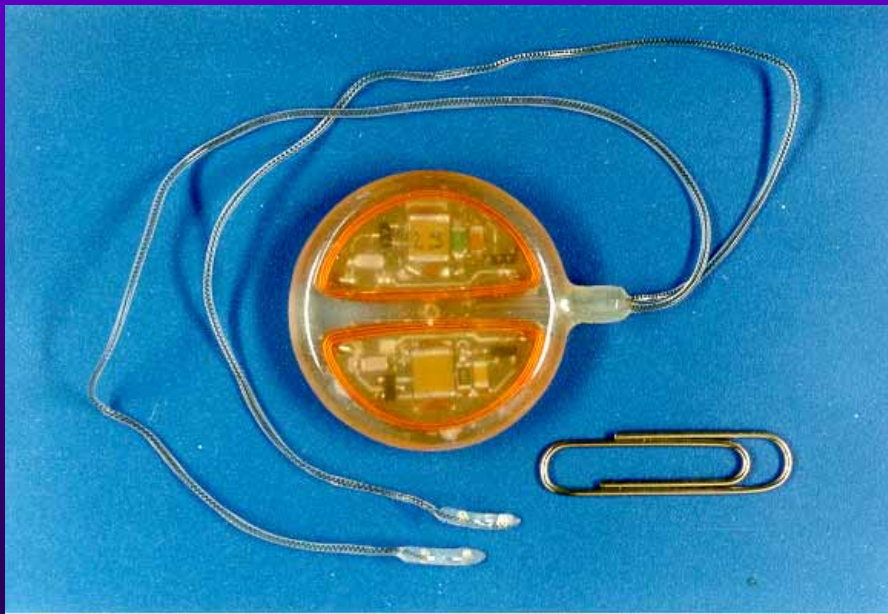
# Stim-U-Step

- 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 Feb 08

- 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 <sup>1</sup>/<sub>2</sub> 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<sup>1</sup>/<sub>2</sub> 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



# 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

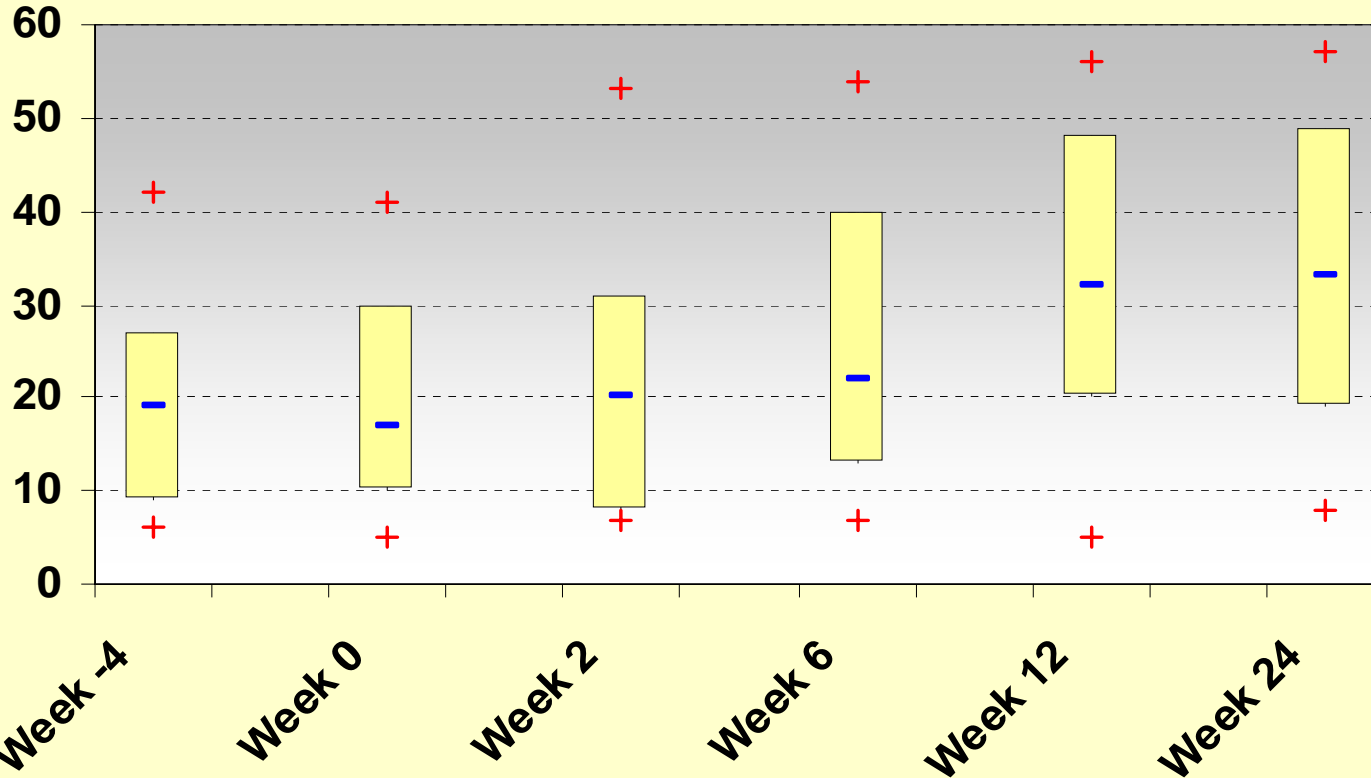
- Assistance to reach and open the hand in response to attempt to make movement



Funded by The Stroke Association

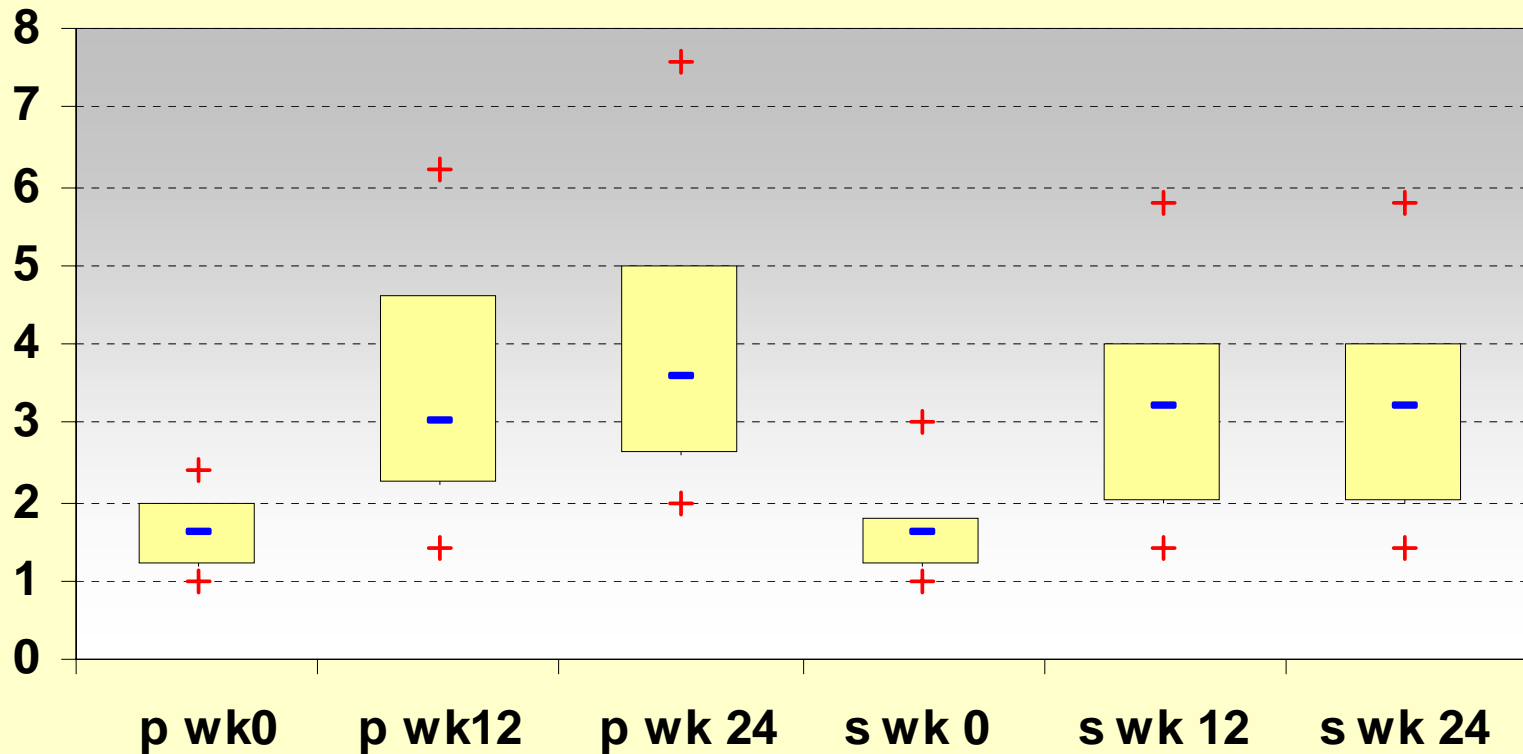
# Accelerometer triggered hand stimulator

**Action Research Arm Test (ARAT)**  
(max. possible score 57)



# Hand Stimulation 2

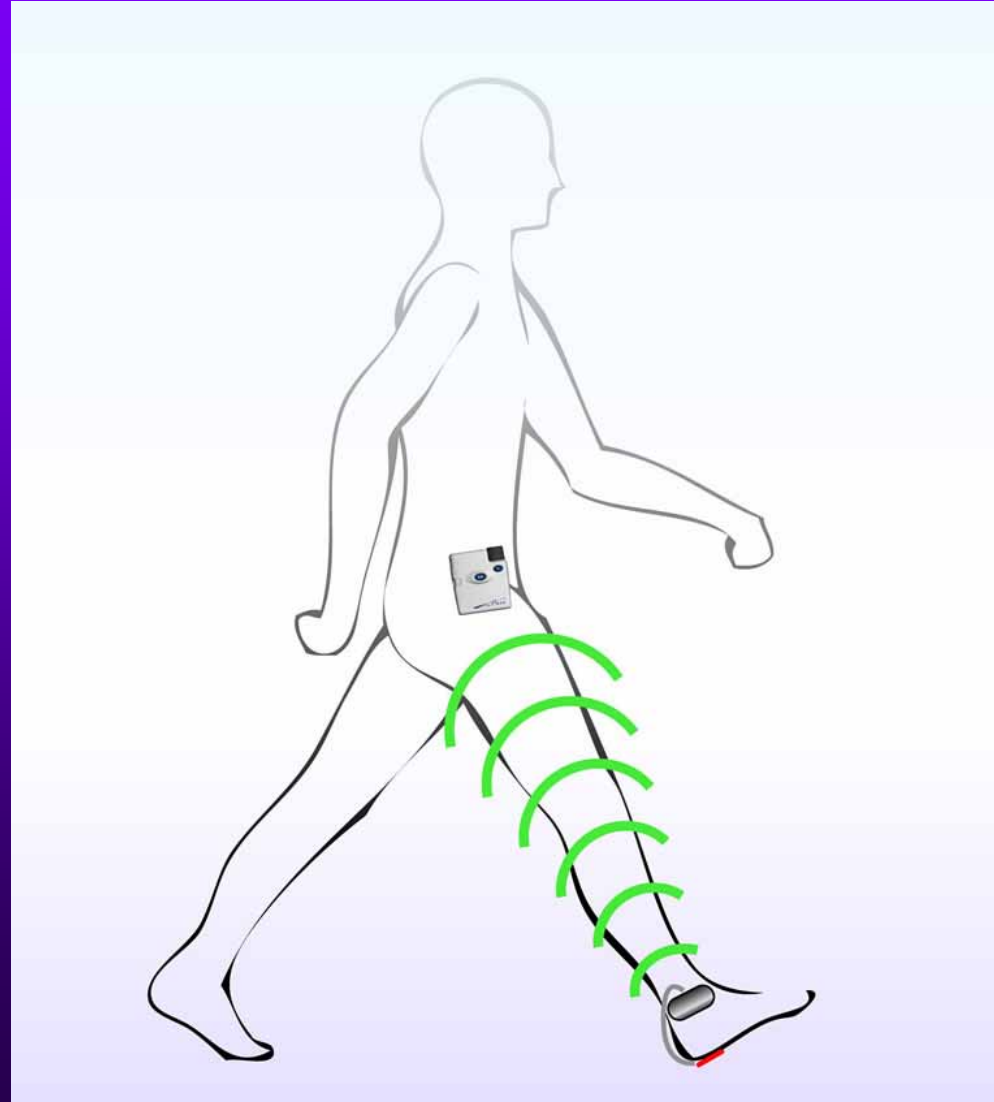
Canadian Occupational Performance Measure (COPM) - performance (p) & satisfaction (s) scores



# ODFS - *Pace MiWi*

## Main Features

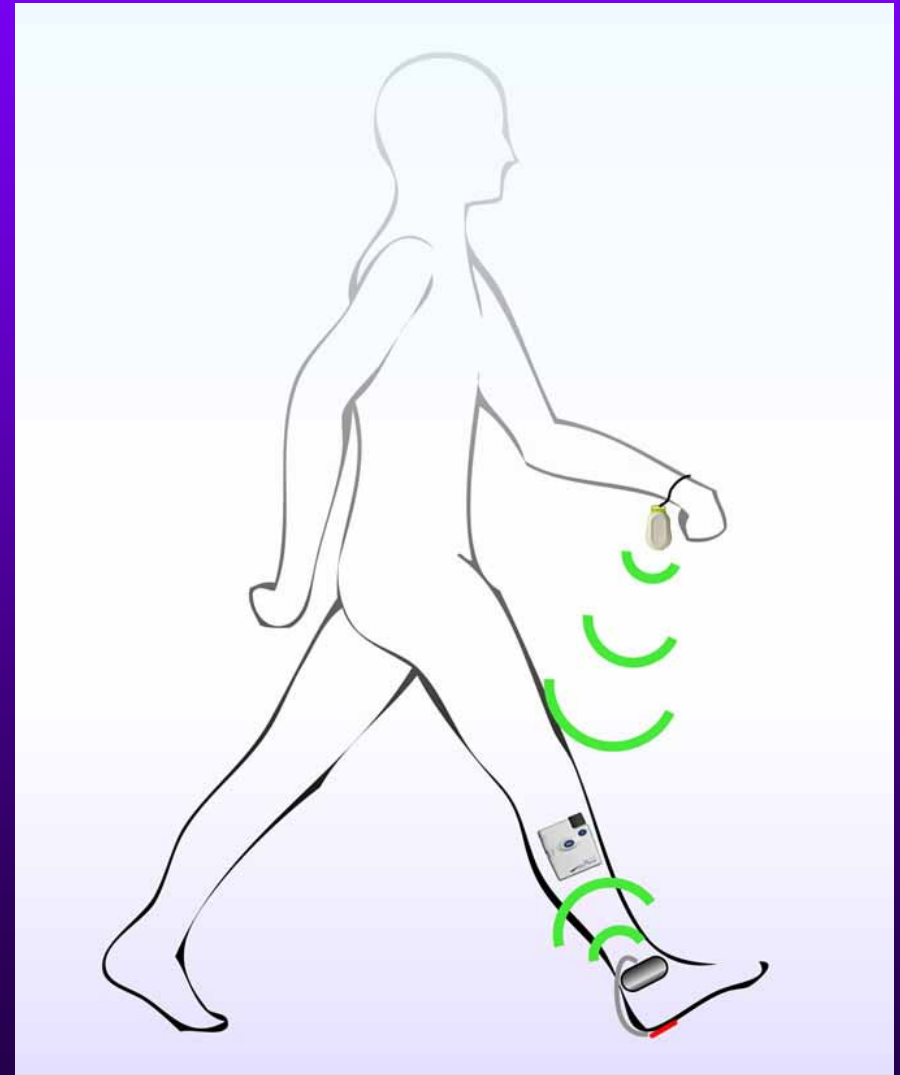
- Wireless foot-switch



# ODEFS - *Pace MiWi*

## Main Features

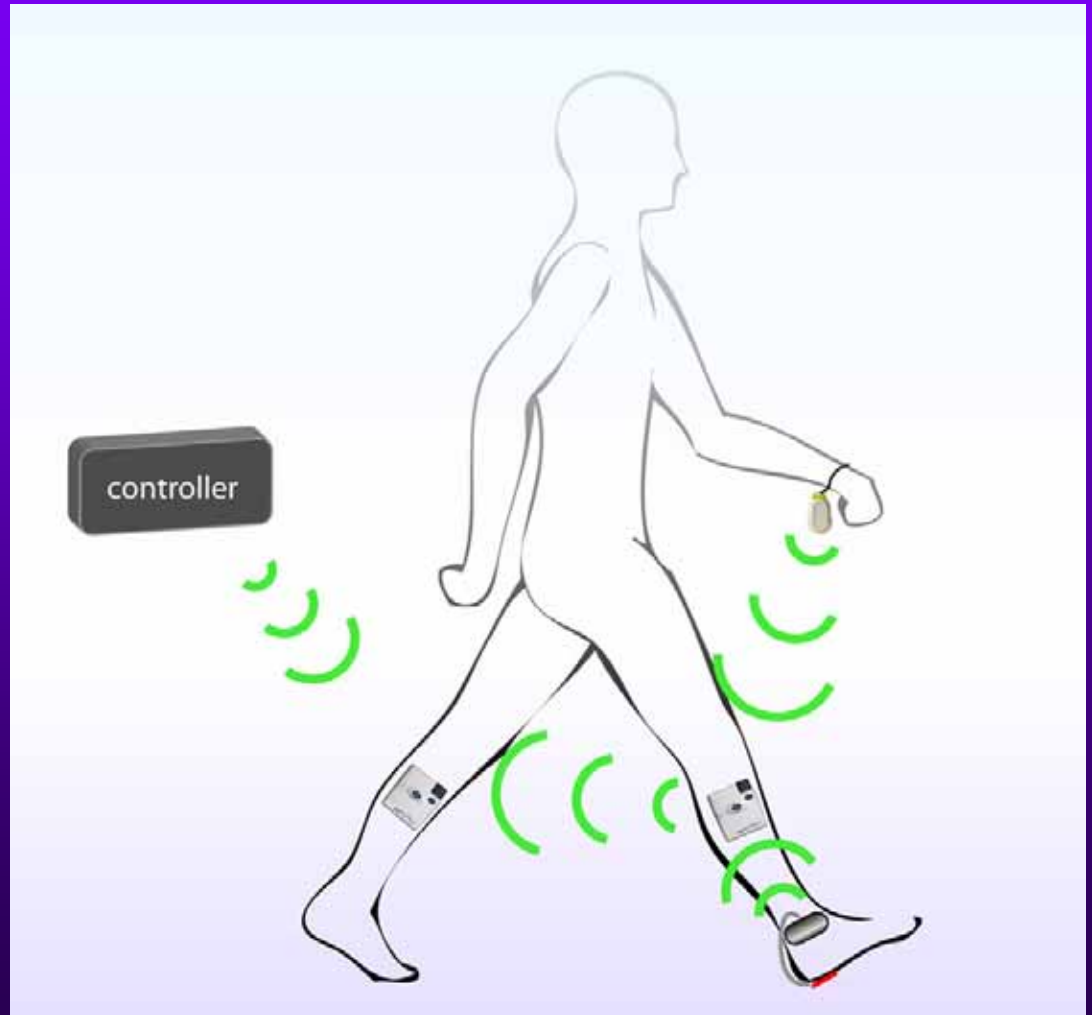
- Wireless remote control



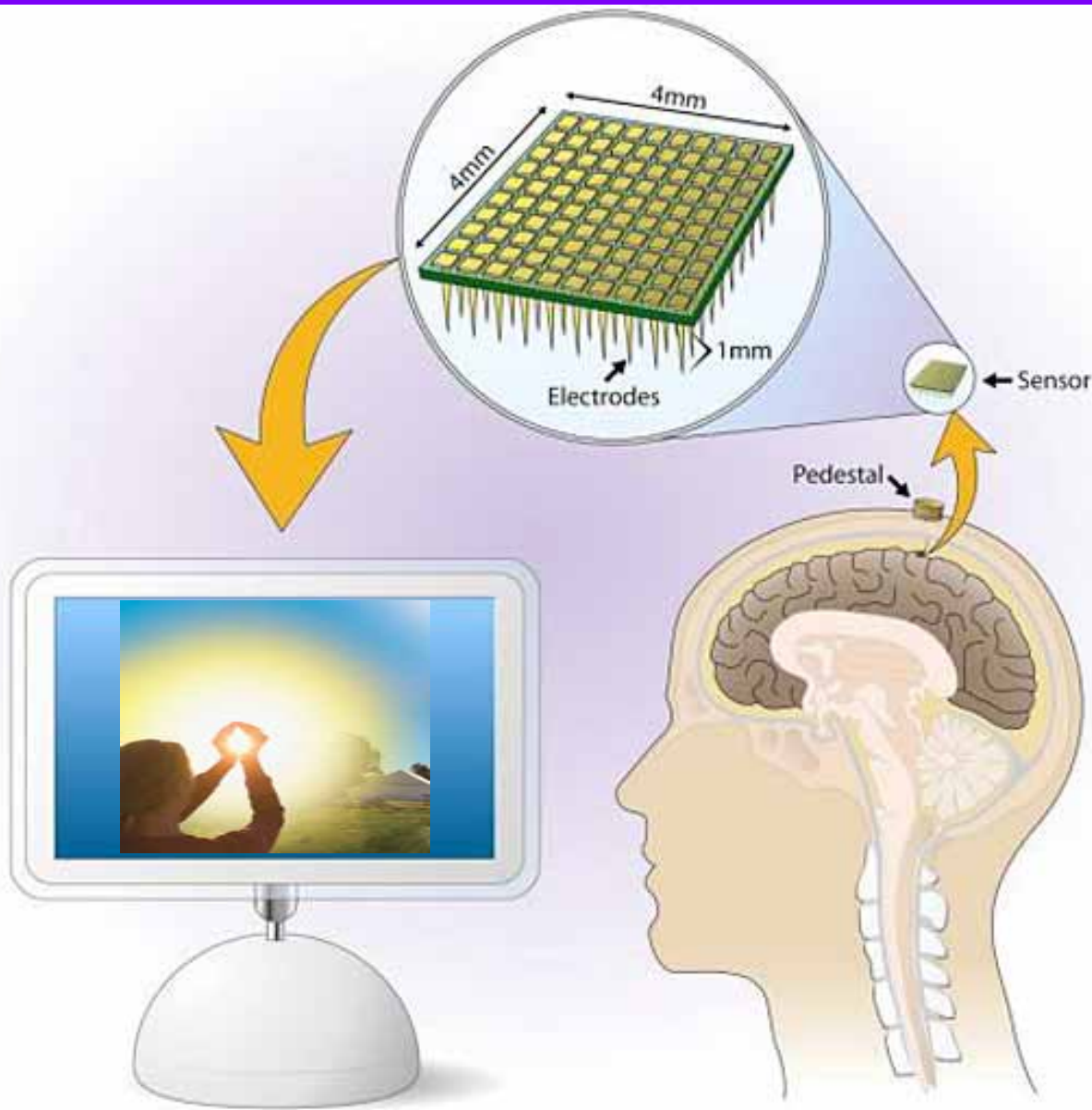
# ODEFS *Duo Pace MiWi*

## Main Features

- Wireless future



# Longer term future



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