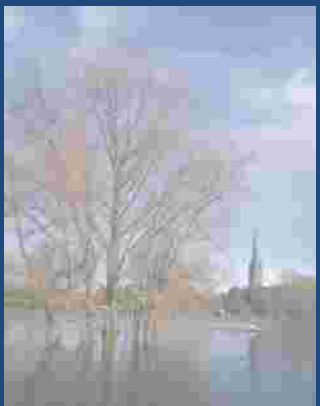


A comparison of external and implanted FES for correction of dropped foot in MS. An audit of the STIMuSTEP service in Salisbury

Taylor P, Wilkinson I, Samuel V, L Kwan, Humphreys L, Slade-Sharman D, Khan M and Hobby J.

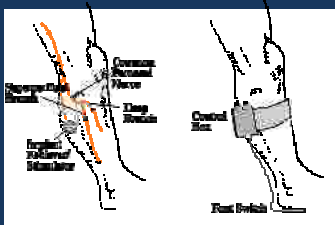


STIMuSTEP
Implanted Dropped Foot Stimulator


Why use an implant?

- Removes need to position electrodes each day
- Removes the possibility of skin irritation
- Reduced sensation
- Reduced wires
- Increased convenience
- 66% of ODFS users said they would like one (survey of 140)





Independent stimulation of deep and superficial branches of the common peroneal nerve for separate control of dorsiflexion and eversion




Patient selection for STIMuSTEP

The selection criteria for STIMuSTEP are the same as external FES with the following additions:

- Demonstrate suitability by using external FES for 6 months
- Stable and likely to be long term users of FES
- Issues that prevent consistent use of external FES
 - Persistent skin irritation
 - Difficulty using external equipment e.g. cognitive issues or problems using hands
 - Difficulty reliably locating electrodes
- Not diabetic or using immunosuppressive drugs

MS EDSS 4
Has now used SuS for 5 years



20 week follow up

- 16% increase in walking speed
- 14% fall in Physiological Cost Index (effort of walking)
- 16% increase in 3 min walking distance



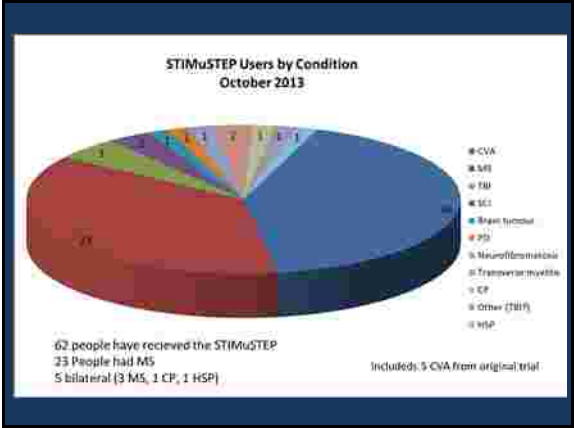
Procedure

- Assessments
 - 10m walking speed
 - 3 min walking distance
 - PCI
 - PIADS
 - Use of device questionnaires

STIMuSTEP Time-Line

Timeline events: ODFB, Pre Op assessment, 5 weeks training, STIMuSTEP group, Walk up assessment, STIMuSTEP, Post op assessment.

Weeks: week 0, week 5, week 10, week 15, week 20.



Reasons for going for the implant

- skin irritation 44%
- difficulty placing electrodes 24%
- convenience 10%
- difficulty with wires etc. 7%
- participant in research 12%
- other 2%

MS Cohort n = 23

- Mean time external FES used prior to SuS - 30.1 months (SD 21.5)
- Mean age at assessment - 56.1 years (SD 11.1)
- Mean time since diagnosis 15.9 years (SD 10.6)
- Mean time between pre op assessment and SuS setup - 5.2 months (SD 3.0)
- Mean time between set up and 2nd assessment - 3.7 months (SD 1.1)
- Mean total SuS use (Oct 2013) - 45 months (SD 24, range 8 to 93)

Walking speed ms⁻¹

Both devices increase walking speed by the same amount
p=0.77

Change pre to post op
No FES -0.06, p=0.06
With FES -0.06, p=0.05

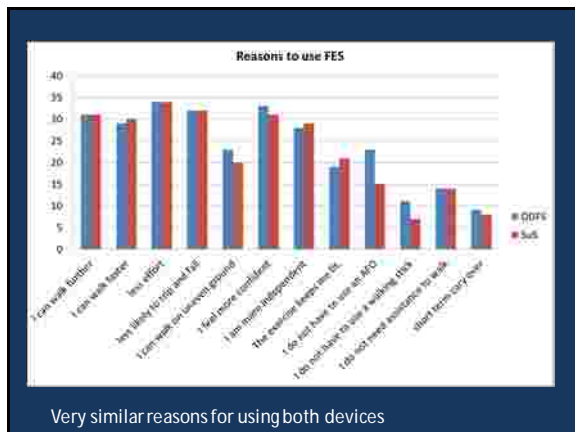
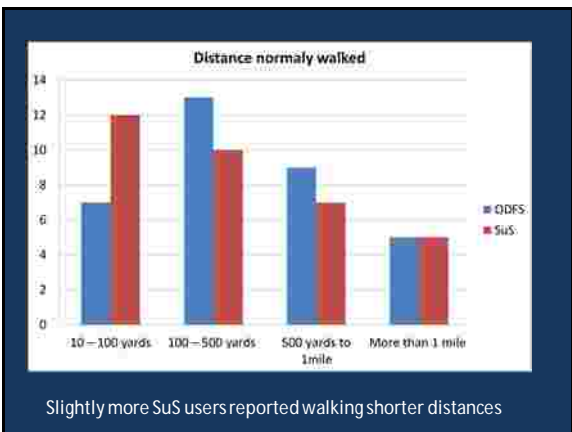
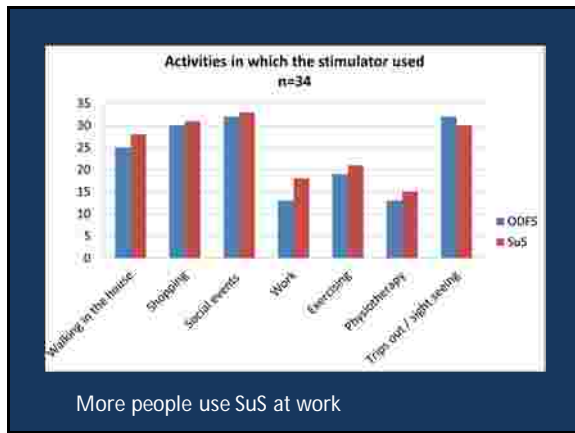
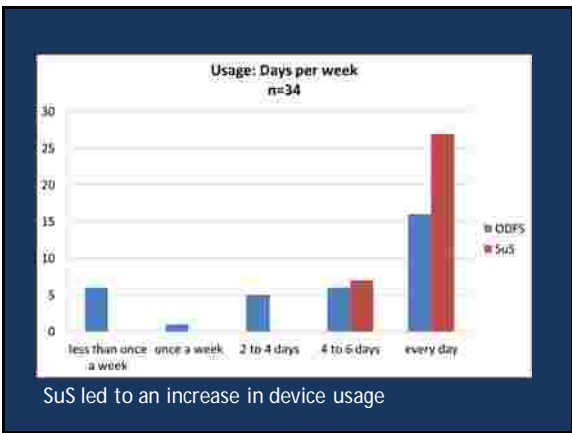
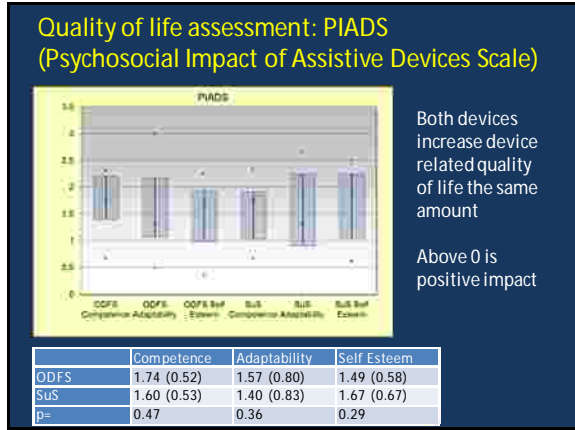
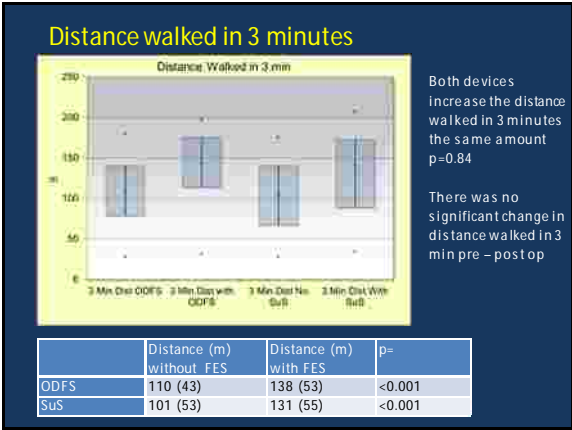
Walking was slower post op (9 months later)

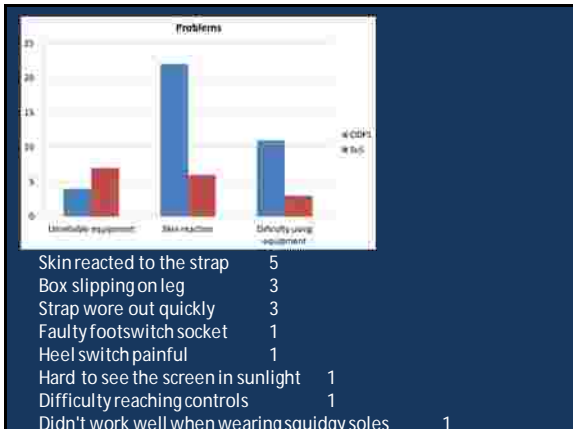
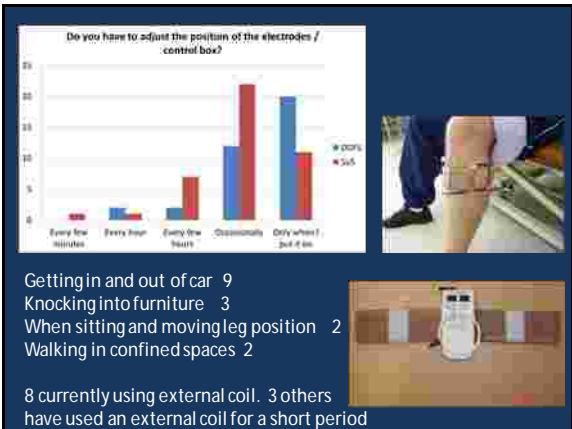
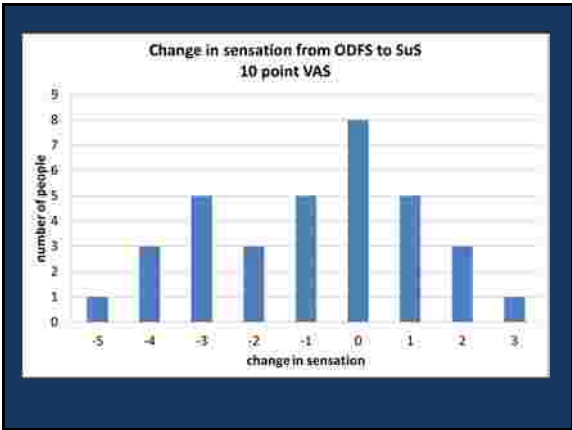
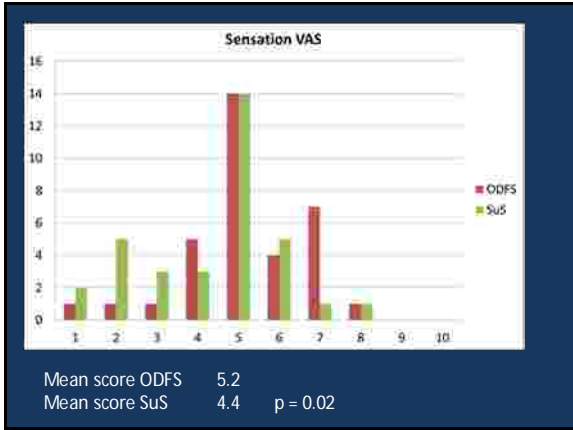
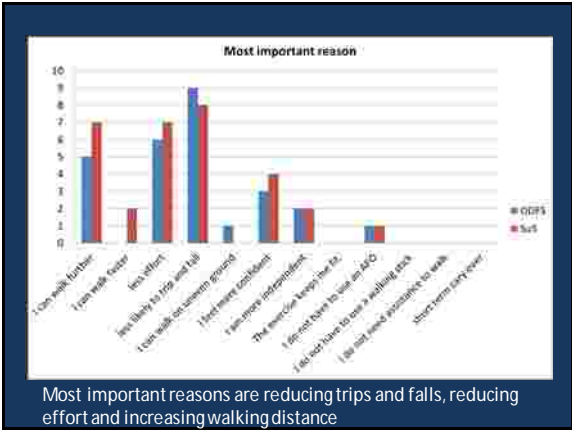
Mean (SD)	Speed (ms ⁻¹) Without stim	Speed (ms ⁻¹) With stim	p = (t test)
ODFS	0.70 (0.26)	0.85 (0.28)	<0.001
STIMuSTEP	0.64 (0.29)	0.79 (0.28)	<0.001

Physiological cost index (PCI)

Both devices decrease PCI by the same amount
p=0.91

	PCI (bt m ⁻¹) Without stim	PCI (bt m ⁻¹) With stim	p =
ODFS	0.58 (0.57)	0.48 (0.42)	0.017
STIMuSTEP	0.57 (0.46)	0.49 (0.52)	0.039





How long does it take you to put the FES equipment on?

- ODFS 11.7 minutes
- SuS 2.3 minutes (p<0.001)

Adverse effects (MS)

- 4 implant failures
 - 3 revised
 - 1 waiting revision
- 2 cases of neuropraxia
 - Both cases resolved

Conclusions

STIMuSTEP is functionally Equivalent to external FES

STIMuSTEP provides a solution for people who have problems achieving reliable use from external FES

There is a risk of short term nerve dysfunction and implant dysfunction

User satisfaction is high



EDSS 6
 49% increase in walking speed
 32% fall in PCI
 71% increase in 3 min walk distance
 Used 2.5 years