Use of Functional Stimulation (FES) for chronic constipation & People with Multiple Sclerosis (PwMS)

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(FES User Day 8th Dec 2017)
Research idea

• The problem
• Novel use off FES
• Pilot results
• Next steps
PwMS (n=107K) & Chronic Constipation

- Constipation more common than incontinence – often linked
  - 50%+ PwMS prone to constipation (5% of general population)
  - 30 – 40% prone to incontinence (2% of general population) Hinds et al (1990)

- £10.4m spent on emergency B & B admissions in England (2015/16) (www.mstrust.org.uk/ms-admissions)

- PwMS have 2-3 x more admissions for impaction, megacolon and constipation than other non-neurological conditions. DasGupta et al (2003), Wiesel et al (2001)

- Has major impact on QOL with 15% reporting ceasing employment. Social isolation & impact on families significant Norton et al (2010)

- Healthcare & personal costs eg: embarrassment, comfort time & resource
Management of constipation

- **Little or no research** (Coggrave et al 2003)

- **Increasing** dietary fibre is often ineffective & without peristalsis increases flatulence and bloating (Weisel PH et al. 2001)

- Mild stimulant/osmotic laxatives or suppository/enemas may be **used for a few weeks** to establish a regime

- Establish a **predictable regime/pre-emptive approach** – complete a diary


- **Rarely surgery** – colostomy, ileosostomy, implanted nerve stimulators
Common use of FES

• Dropped foot & other functional stimulation of lower limb

• Exercise stimulation for Upper and lower limbs
Case Report then Pilot Study

• Case report of Person with Multiple Sclerosis (PwMS) successful treatment of Chronic Constipation with FES


July 2013 Ethics approval for 5 x PwMS prospective pilot study using FES to bilateral abdominals
Criteria

• Inclusion criteria
  – Diagnosis of MS
  – Rome III criteria for functional constipation
  – Constipation history of at least 3 months

• Exclusion criteria
  – History of irritable bowel syndrome
  – Organic bowel obstruction
  – Contraindications for FES
  – No previous FES application
Outcome Measures

Objective

- Smartpill wireless motility capsule for gut transit time
  - Swallow protocol
  - Link with wearable monitor
  - Expelled
**SmartPill GI Monitoring System Components**

The main components of the SmartPill GI Monitoring System are the pH.p Receiver, Docking Station, System Computer, MotiliG1 software, and Smart a brief introduction to each component’s features and functions.

**pH.p Capsule**

![Figure 1 - pH.p Capsule](image)

The pH.p Capsule is a single-use device that measures pressure, pH, and te SmartPill sensor technology provides information that aids clinicians in the and offers a patient-friendly alternative to other tests such as gastric emptyi duodenal manometry.
Outcome Measures

Subjective

- Patient assessment of constipation QoL (PAC-QoL)
- Bowel diary
- Medication changes (laxatives)
- The Bristol Stool form scale
# The Bristol Stool Form Scale

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>Separate hard lumps, like nuts (hard to pass)</td>
</tr>
<tr>
<td>Type 2</td>
<td>Sausage-shaped but lumpy</td>
</tr>
<tr>
<td>Type 3</td>
<td>Like a sausage but with cracks on its surface</td>
</tr>
<tr>
<td>Type 4</td>
<td>Like a sausage or snake, smooth and soft</td>
</tr>
<tr>
<td>Type 5</td>
<td>Soft blobs with clear-cut edges (passed easily)</td>
</tr>
<tr>
<td>Type 6</td>
<td>Fluffy pieces with ragged edges, a mushy stool</td>
</tr>
<tr>
<td>Type 7</td>
<td>Watery, no solid pieces ENTIRELY LIQUID</td>
</tr>
</tbody>
</table>
Microstim (MS2) from Odstock Medical Ltd

- Self administered
- Simultaneous contraction
- 40Hz frequency
- 40 – 50 mA output (to comfort)
- 330 µs pulse width
Method

Baseline
- Smartpill provision &
- Subjective outcomes recorded

Treatment period
- Repeat subjective outcomes
- Start 6 weeks of 2 x daily for
  30 mins FES stimulation

Post treatment period
- Smartpill provision
- Repeated subjective outcomes
- Stopped FES
Results
Published in MS International Journal – Singleton.C et al (April 2016)

• 5 female patients recruited
• One withdraw three weeks after start due to relapse of MS
• Mean age was 53.2yrs (range 45-58)
• Mean duration of MS since diagnosis was 22.7yrs (range 8-29)
• No adverse effects reported
• Use of laxatives reduced
• 4 patients continued treatment post pilot study
Total transit time

<table>
<thead>
<tr>
<th>Patient</th>
<th>1st Smartpill pre FES treatment</th>
<th>2nd Smartpill post FES treatment</th>
<th>improved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
<td>124</td>
<td>81</td>
<td>43</td>
</tr>
<tr>
<td>Patient 2</td>
<td>118</td>
<td>78</td>
<td>40</td>
</tr>
<tr>
<td>Patient 3</td>
<td>141</td>
<td>70</td>
<td>71</td>
</tr>
<tr>
<td>Patient 4</td>
<td>117</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 5</td>
<td>201</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Worst, 201 hrs = 8.4 days
Best, 70 hrs = 2.9 days
<table>
<thead>
<tr>
<th>Patient</th>
<th>Baseline TGTT (hrs)</th>
<th>Post FES TGTT (hrs)</th>
<th>Baseline CTT (hrs)</th>
<th>Post FES CTT (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>124.02</td>
<td>81.22 (35% ↓)</td>
<td>115.41</td>
<td>70.09 (39% ↓)</td>
</tr>
<tr>
<td>2</td>
<td>118.29</td>
<td>78.53 (33% ↓)</td>
<td>109.09</td>
<td>55.40 (49% ↓)</td>
</tr>
<tr>
<td>3</td>
<td>141.44</td>
<td>70.04 (50% ↓)</td>
<td>132.15</td>
<td>62.18 (53% ↓)</td>
</tr>
<tr>
<td>5</td>
<td>201.27</td>
<td>146.23 (27% ↓)</td>
<td>190.43</td>
<td>128.06 (32% ↓)</td>
</tr>
<tr>
<td>Item of bowel diary</td>
<td>Patient 1</td>
<td>Patient 2</td>
<td>Patient 3</td>
<td>Patient 4</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>Straining to open bowels (4/4 pts improved)</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
</tr>
<tr>
<td>Passing hard, lumpy stools (3/4 pts improved)</td>
<td>-0</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
</tr>
<tr>
<td>Incomplete bowel evacuation (3/3 pts improved)</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
<td>+0</td>
</tr>
<tr>
<td>Feeling of “blockage” in bowels (3/4 pts improved)</td>
<td>-0</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
</tr>
<tr>
<td>Use of manual evacuation of bowels</td>
<td>+1</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Frequency of bowel motions (3/3 pts improved)</td>
<td>+0</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
</tr>
<tr>
<td>Number of loose stools per week 1 pt = worse</td>
<td>+0</td>
<td>-1</td>
<td>+0</td>
<td>-0</td>
</tr>
</tbody>
</table>
A reduction in score = greater QoL

<table>
<thead>
<tr>
<th>Patient</th>
<th>Baseline score</th>
<th>Post FES treatment score</th>
<th>Score difference reduced from baseline</th>
<th>1.5 - 2 years post Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.14</td>
<td>0.71</td>
<td>0.43</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1.86</td>
<td>1</td>
<td>0.86</td>
<td>1.28</td>
</tr>
<tr>
<td>3</td>
<td>1.86</td>
<td>0.71</td>
<td>1.15</td>
<td>0.71</td>
</tr>
<tr>
<td>4</td>
<td>1.57</td>
<td>0.86</td>
<td>0.71</td>
<td>1</td>
</tr>
</tbody>
</table>

None have returned to BL data. All maintained improvement & satisfied with regularity.
Statistical significance

- Bootstrap for Paired Samples test
  - TTGT, $p = 0.053$
  - Large effect size $d = 3.72$

- CTT, $p = 0.001$
  - Large effect size $d = 5.81$

- QoL, $p = 0.001$
  - Large effect size $d = 3.19$
Additional case series of 10 pwMS using FES followed

At baseline median number of constipation related issues (PACQoL) identified = 17 at baseline (interquartile range 21.25 - 1.75)

After 6 weeks Rx reduced to 2 issues (IQR 10.75- 1)

Long term users were observed to titrate the frequency and duration of FES as required.

three long-term users (2-3 years) reported no longer experiencing constipation symptoms and no longer used any form of treatment.
Next step

- Findings show FES applied to abdominal muscles improved gut motility which was sustained over time
- All patients reported better QoL and chose to continue with treatment post trial
- Mechanism by which FES improved gut motility not clear
  - Strengthened abdominal muscles?
  - Increased intra abdominal pressure?
  - Direct effect on peristalsis?
- Research for Patient Benefit (RfPB) (NIHR) funding request submitted
- 2 centred feasibility study, RCT, n= 52, 20 weeks study time per participant, total study time = 2 yrs
- Beneficial for other pathologies?
Special acknowledgements

- Carla Peace
- Paul Taylor
- Tamsyn Street
- Members of FESCaMS research team
- Prof M Bakheit

Thank you for listening
Any questions?