

CLINICAL FOCUS TOPIC #1

Transcutaneous Sacral Stimulation for FI

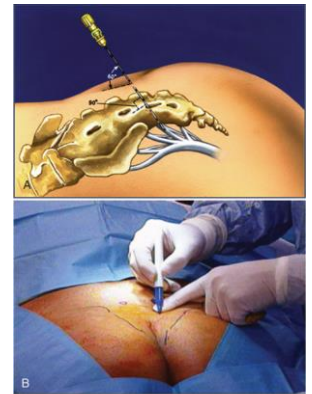
BACKGROUND – Implanted Sacral Stimulation for Faecal Incontinence

Implanted Sacral Stimulation (Interstim™, Medtronic Inc.) has now had numerous randomised controlled trials validating its effectiveness for the treatment of faecal incontinence. Patients can undergo a two-step procedure of a trial implant through the S3 foramen, followed by a permanent implant with a generator inserted in the upper buttock.

The mechanism underpinning the improvement in symptoms is still not fully understood, but may involve a combination of neuromuscular facilitation of the anal sphincter complex, combined with a normalisation of antegrade and retrograde peristaltic waves through the colon.

Whatever the mechanism however.... The question many physiotherapists are asking is whether Transcutaneous Stimulation may be an effective treatment without the associated risks of an implanted lead and generator.

In Newsletter # 1 of 2012 (can be found in Dropbox) I reviewed some of the recent research on Transcutaneous Tibial Nerve Stimulation – behind the medial malleolus – for faecal incontinence. Both implanted sacral stimulation and Tibial Nerve stimulation are thought to work via the S3 nerve root / dermatome (respectively).



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So Can direct SACRAL TENS over S3 assist with faecal incontinence?



FOCUS TOPIC - Transcutaneous Sacral Nerve Stimulation for Faecal Incontinence.

To date there have only been three research trials looking at Sacral TENS for faecal incontinence (*to my knowledge*).

1. **Chew, Sundaraj and Adams 2011**, Sacral transcutaneous electrical nerve stimulation in the treatment of idiopathic faecal, incontinence. *Colorectal Disease*, vol 13, pp. 567 – 571
2. **Leung and Francombe 2013**, Preliminary Results of Sacral Transcutaneous Electrical Nerve Stimulation for Fecal Incontinence, *Diseases of the Colon and Rectum*, vol 56, no. 3.
3. **Thomas, Norton, Nicholls and Vaizey 2013**, A pilot study of transcutaneous sacral nerve stimulation for faecal incontinence. *Colorectal Disease*, Aug, epub ahead of print.

SUMMARY OF TRIALS ON SACRAL STIMULATION FOR FECAL INCONTINENCE

	Chew et al 2011		Leung et al 2013		Thomas et al 2013	
Number of Participants	n = 17		n = 20		n = 10	
TENS Pads – Location	2 square electrodes 3cm x 3cm At S3:		2 square electrodes 3cm x 3cm At S3: 3-4cm apart		4 rectangular electrodes 10cm x 5cm Over whole sacral area	
TENS Settings	10Hz 200ms Continuous Intensity Tingling sensation		10Hz 250ms Continuous Intensity Tingling 10-30mA		14Hz 210ms Continuous Intensity Sub-sensory	
Length of TENS sessions	2hours per day		2hrs morn. & afternoon (day 1 & 2) 3hours morn. & afternoon (day 3 & 4) 8hours per day (day 5 Onwards)		12hours per day	
Duration of Rx	<u>3.5 months</u>		<u>1 month</u> Cease at 1month if not improving Continue - but gradually wean down time if significant improvement		<u>1 month</u>	
	RESULTS					
	<u>FI Episodes per week</u> Pre Post		<u>St Mark's / Vaizey FI Score</u> Pre Post		<u>FI Episodes per week</u> Pre Post	
	19.7	12.1 (3/12 post Rx)	12.7	5.8	9.5	3
	<u>FI Severity Index</u>		<u>Wexner Score</u>		<u>Time able to Defer</u>	
	40.9	3/12post Rx: 28.3 Long Term: 24.8	7.9	4.0 (50% improved)	1min	4.5min

Taryn's Comments:

METHODS

At present we only have 3 published trials on the use of transcutaneous sacral nerve stimulation for faecal incontinence. Unfortunately, all three trials are of small numbers and **none of the trials had a control group**. Therefore the possibility of a placebo effect needs to be considered. The good news is that each of the authors (particularly Thomas et al 2013) have indicated that they now intend to undertake larger randomized controlled trials.

However, if we take the current research on face value.....

Interestingly, all studies used long term stimulation:

- Chew et al - 2 hours per day
- Leung et al - 8 hours per day and
- Thomas et al - 12 hours per day

In addition, all the studies used a **10-15Hz frequency** with a **200-250ms pulse width**.

RESULTS

Whilst the results presented show an improvement, they don't seem to show a high rate of cure. With that said, the treatment duration was fairly short (1-3 months) and Thomas et al indicated in their discussion that 2 out of 10 patients were actually completely continent after 1 month.

What makes the results more impressive though is that all the studies had an inclusion criteria that the patients had previously failed medical therapy and physiotherapy with biofeedback. These were therefore a "hard to cure" cohort.

Another interesting finding is that of Chew et al 2011. Whilst the initial therapy was only 3.5 months, patients either maintained their improvement or improved further in the 12-18 months after treatment finished.

FINAL SUMMARY

The research on Transcutaneous Sacral stimulation for faecal incontinence is obviously in its early days. However, as it is basically a "risk-free" treatment (assuming standard TENS contra-indications have been checked), I would think it is worth trying in this cohort of patients in whom other therapies have failed.

Long term it would also be interesting to find out whether sacral TENS has any predictive value in determining which patients may improve with implanted sacral stimulation. If it was found to be predictive, this may then hopefully reduce the need for trial implantation of Interstim in patients likely to be unresponsive to this type of management.