Peer reviewed article

**Strengthening of the pelvic floor muscles using transcutaneous magnetic nerve stimulation: a review of the literature**

**Abstract**

This review summarises the biophysics of transcutaneous magnetic nerve stimulation (TMNS), the theoretical basis for application of TMNS to achieve strengthening of the pelvic floor in the management of incontinence, current physiotherapy practice and a review of published results from research studies into the clinical application of TMNS. It is concluded that, at present, there is insufficient evidence to suggest that TMNS is a suitable, alternative method for strengthening the pelvic floor. Nor is it a suitable method to improve the functional status of individuals with incontinence when compared to traditional continence management involving exercise, transcutaneous electrical nerve stimulation and biofeedback.

**Introduction**

Bickford & Fremming first demonstrated neuromuscular stimulation by magnetic fields in 1965, and the first clinical application of magnetic fields for stimulating pelvic floor muscles (PFMs) was by Galloway et al. in 1999. This 1999 study involved use of the Neocontrol® pelvic floor therapy system [Neotonus Inc, Marietta, Georgia, USA] in the treatment of incontinence.

This ‘therapy system’ comprises a wooden chair incorporating a coil within its seat that generates a magnetic field capable of penetrating the pelvis. If the intensity is sufficient, this magnetic field-generating chair can produce a contraction of the PFMs. Advocates of the Neocontrol® chair have made claims about its efficacy which deserve critical analysis and further research.

The aim of this paper is to introduce some of the key issues that need to be considered when evaluating this relatively new method of treatment. Supported by a literature review, attention will be given to two categories of evidence – first, the available scientific evidence and related logical arguments and, second, clinical research findings.

**Physics of magnetic fields**

Traditionally, the direct application of electric current through the surface of the body has been the main alternative to voluntary exercise for achieving muscle contractions (by stimulating the muscle's nerves) for therapeutic purposes but it is also possible to use magnetic fields. Faraday's law of magnetic induction indicates that a changing magnetic environment in the vicinity of an electric conductor causes an electric current to be induced in that conductor. Transcutaneous magnetic nerve stimulation (TMNS) involves use of a magnetic field generator located outside the body to induce current within the body. The terms ‘static’ and ‘time-varying’ apply to magnetic fields which have, respectively, a constant and continuously changing output. Time-varying magnetic fields are more convenient and effective clinically because they allow rest periods between induced muscle contractions, and thereby minimise fatigue.

**Biophysics of TMNS**

The available evidence points to the induced current acting primarily on the membranes of nerves. Accordingly, muscle contraction resulting from TMNS is most likely caused by depolarisation of motor nerves. The frequency and other time-characteristics of the electric current induced in the distribution of the magnetic field has the same time characteristics as the magnetic field; that is, if 50Hz magnetic field is used, the induced electric current has a frequency of 50Hz.

Whether a nerve in the magnetic field is activated depends on the strength of the field in the vicinity of the nerve and the discharge capabilities of the nerve. Motor nerves supplying postural muscles such as soleus produce complete tetanic contractions when they discharge at relatively low frequencies (~25Hz). By contrast, predominantly phasic muscles are completely tetanised...
when their motor nerves discharge at ~50Hz. These values also apply to the postural (type 1) and phasic (type 2) motor units of levator ani and related sphincters. Note that the PFMs contain more type 1 than type 2 muscle fibres, especially in and around the sphincters.7.

The use of electric current, as in transcutaneous electrical nerve stimulation (TENS) to stimulate PFM has a long history, as does therapeutic exercise8-9. Therefore, evaluation of TMNS should be undertaken in comparison to the value of TENS and exercise. For example, it should be appreciated that both TENS and TMNS ultimately cause PFM contraction via an electric current, and it is merely the way in which current is generated in the vicinity of the PFMs that differs in the two approaches.9.

### Methodology

For purposes of evaluating the clinical benefits of pelvic floor TMNS for this paper, an examination was made of the reference material put together by the Neotonus Corporation in support of their apparatus. An internet literature search was undertaken to locate research trials and reviews of pelvic floor magnetic field stimulation in the years 2000-2005. The PubMed, NLM, OVID CINAHL and Web of Science databases were searched for papers relevant to this topic. The premise of the literature review was that the standing of TMNS could be reliably characterised by critical analysis of this key current literature.

A comparison of TENS versus TMNS

The manufacturer of the Neocontrol® pelvic floor therapy system has described poor PFM contraction, that is, lack of strength, as the main indication for use of the apparatus. It also suggest it may be used to relieve pain.

When electric current (TENS) is used to stimulate PFMs, use is typically made of a perineal, intravaginal or rectal electrode. The part to be treated must be exposed, and the vaginal or rectal tissue must be sufficiently healthy to tolerate the electrode application. Nevertheless, this electrode placement helps the physiotherapist focus the current in the region of the pelvic floor. In addition to electrode location, the path of this electric current through the pelvis is determined by the ohmic resistance (water content) of the tissues. Thus, the electric current tends to follow the path of major blood vessels, well-vascularised muscles and the related nerves.

In contrast to electric current, magnetic field therapy does not require exposure of the part, has no direct coupling of the magnetic applicator to the patient, and involves production of an energy field which is relatively evenly distributed throughout the tissues through which it passes and dissipates according to the inverse square law. It seems, that the greatest concentration of magnetic energy will be close to the generator, which may result in excessive stimulation of cutaneous nerves or unwanted stimulation of motor nerves innervating the gluteal muscles or other unwanted muscles such as hamstrings.2.

It follows from the above that stimulation of PFM, whether by TENS or TMNS, should be administered with care by an
experienced clinician capable of assessing for and ensuring benefit.

The manufacturer of the Neocontrol® system advocates use of the apparatus as the “first line treatment of choice for stress, urge and mixed incontinence”. It is, however, questionable whether, within the limits of patient comfort, the magnetically-evoked PFM contraction can be made sufficiently intense, or prolonged, to significantly improve strength or endurance; especially since the manufacturer information recommends that the subjects not attempt concurrent voluntary contractions during TMNS treatment. This is in contrast to the long-established practice of having patients voluntarily contract muscles simultaneously with TENS-evoked muscle contractions 4(p224).

As noted by Evans 10, magnetic fields may excite autonomic as well as somatic nerves. While normal micturition undoubtedly depends on the combined influences of somatic efferent, somatic afferent and autonomic efferent nerves, the balance of stimulation of these three categories of nerve by magnetic stimulation has not been adequately researched, and is at present largely in the realm of speculation. To a large extent, the same may be said of electrical stimulation, although there is some research supporting the use of electric current at particular frequencies (5-10Hz) for achieving reflex inhibitory effects on the detrusor 11.

Regarding the use of TMNS for pain relief, two papers that advocate this 12, 13 offer no explanation as to how pain relief may occur. Nevertheless, by analogy with the explanation for TENS 14, a likely mechanism is explained by the gate-control theory of pain relief 4(p261). This theory proposes that the stimulation of large diameter (proprioceptive) afferent nerves causes blocking of small diameter pain afferent transmission through the dorsal horn of the spinal cord.

Application and dosage

To receive treatment, the fully-clothed patient sits in a timber chair specially constructed with the magnetic applicator incorporated into the seat. Since the chair seat is flat, the patient is not constrained to sitting on a particular part of the chair seat nor sitting in a particular posture. The control unit, about the size of a brief case, rests on a small trolley beside the chair. Contraindications given by the manufacturers of the Neocontrol® system are pregnancy, cardiac pacemaker, implanted (metallic) pelvic devices, pelvic infection, pelvic surgery (within the previous 6 months), an abdominal insulin pump in situ and any external monitoring device. These
contraindications are in keeping with the list generally cited for TENS stimulation.4(p244).

The dosage for treatment with the Neocontrol® apparatus is, to a large extent, controlled by a patient prescription card that must be inserted into the treatment console. The only readily available card that is provided programs the apparatus to deliver 10 minutes of pulsed energy at 10Hz followed by 10 minutes at 50Hz. Although other cards with different prescriptions can be purchased on request, the 10Hz and 50Hz card appears to have been universally accepted. The only parameter that can be controlled by the clinician with the apparatus in its present form is magnetic field intensity. The manufacturer recommended a total programme of 2x20 minute treatments per week for 8 consecutive weeks. However, despite no evidence based rationale for this dosage, it continues to be ‘routinely’ used in a majority of the published clinical research trials.

When using the Neocontrol® system for the purpose of treating stress incontinence via PFM strengthening, the manufacturer’s recommendation is to advance the intensity as much as possible within the limits of patient comfort, and to sustain this maximum comfortable intensity for two periods of 10 minutes. Additionally, based on limited research with experimental animals,2,11,15, the higher frequency (50Hz) is being advocated for stress incontinence, and the lower frequency (10Hz) for urge incontinence. The higher frequency is also being recommended for pain relief.

A key benefit expounded by the manufacturer is that this apparatus can provide a benefit independent of patient compliance – the patient is not only expected, but actually required to sit inactively throughout the treatment, and should not attempt to voluntarily contract the PFM.

Discussion

How TMNS varies from current physiotherapy practice

If it is accepted that different nerve fibres, or different proportions of nerve fibres, are affected by different magnetic field frequencies, the use of a prescription card that imposes a fixed period of 10 minutes at 10Hz and 10 minutes at 50Hz is in fact a ‘recipe’ card. Because of this card, the clinician cannot choose an optimum combination or combinations of duration and frequency for the intended therapeutic efficacy, nor can clinicians select a suitable balance of stimulation and rest. For these reasons, it might be asked whether use of this apparatus with such constraints is ethical.

Regarding the designated aim of increasing PFM strength, the TMNS treatment should be viewed as a form of exercise which follows the well-founded physiotherapeutic principles of exercise and exercise dosage. A particularly important principle is that, for any exercise to be beneficial, it must involve the right muscle or muscles, the right action, and have sufficient dosage.16

As it is presently prescribed, TMNS appears not to adequately address these basic physiotherapeutic principles. First, the patient can sit on the chair in a variety of subtly different postures or postures which may lead to an imbalanced stimulation of the PFMs. It even seems possible that a symmetrically-seated individual may have one or other side of the pelvic floor activated to a lesser extent. In some patients with pelvic floor partial denervation17, excitability of the neural structures and contractile capacity of the muscle may conceivably be different between both sides. In a fully clothed patient, sensation appears to be the only check of the distribution of the effect; yet the sensation experienced within the region of the pelvis does not seem to be given adequate attention by the advocates of this treatment. Within the literature, there is very little known about how and to what extent pelvic sensations correlate with either voluntary or artificially-induced PFM contractions.18

Ten minutes of continuous muscular stimulation at each imposed frequency does not follow accepted principles of strengthening exercise. Strengthening should involve alternating brief strong contractions with interposed rest periods. Ten minutes of the same intensity contraction has more relevance for endurance, but remains less than optimum. Also, 2 x 20 minute sessions per week does not represent optimum dosage for a strengthening or endurance exercise on current evidence-based practice guidelines. For example, a dosage of 3 periods per day for 5 days per week, which represents 4.5% of the total time per week, is a long-believed appropriate dosage for strengthening, and more sessions for endurance. By contrast, the recommended Neocontrol® system dosage of two 20 minute sessions per week represents only 0.4% of a total week.

Percutaneous electrical stimulation to supplement strengthening of weakened muscle in orthopaedics and neurology is administered as a voluntary effort with a superimposed reinforcing electrical stimulation.4(p244). The advantage is that the patient may produce a better magnitude of contraction than that from the current alone, and eventually learn to produce an adequate contraction without the artificial facilitation. There seems no evidence in support of the patient sitting and doing nothing voluntarily during a Neocontrol® treatment; especially if an adequate exercise regimen
<table>
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<tr>
<td>Yamanishi et al. 20</td>
<td>32 patients (17 women, 15 men) with incontinence split into two groups (15 receiving MFS, 17 receiving electrical stimulation)</td>
<td>Chair with magnetic coil similar to Neocontrol system chair For MFS: 10Hz continuous field: no other details given For electrical stimulation: 10Hz: no other details given</td>
<td>No reference made to past or concurrent PFM training</td>
<td>During both treatment types there were improvements in some urodynamic parameters, but no differences existed between the two types of treatment</td>
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<td>Bradshaw et al. 21</td>
<td>18 women with detrusor overactivity. Nine women withdrew from study</td>
<td>Neocontrol system chair 20 min for 6 weeks of 5Hz for 10 min and 50Hz for 10 min</td>
<td>No reference made to past or concurrent PFM training</td>
<td>Increased cystometric capacity in eight of nine subjects at end of treatment programme, but no enduring benefit.</td>
</tr>
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<td>Ünsal et al. 22</td>
<td>52 patients with incontinence (35 stress, 17 urge)</td>
<td>Neocontrol system chair 20 min x 2 weekly for 8 weeks of 5Hz x 10 min and 50Hz x 10 min</td>
<td>No reference made to past or concurrent PFM training</td>
<td>One year after treatment, 81.8% were considered improved or cured; pad weight was significantly reduced, and the Valsalva leak point pressure was significantly increased in the stress incontinence group.</td>
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<td>Almeida et al. 23</td>
<td>91 patients with incontinence (36 stress, 9 urge and 46 mixed)</td>
<td>Neocontrol system chair 20 min x 2 weekly for 8 weeks of 5Hz x 10 min and 50Hz x 10 min</td>
<td>No reference made to past or concurrent PFM training</td>
<td>Immediately after treatment, there was a significant improvement in the quality of life score, number of pads used daily, number of leaks daily, and vesical leak point pressure. One year after treatment, 94% of patients who became dry post-treatment demonstrated recurrence.</td>
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<td>Chandi et al. 24</td>
<td>24 patients with incontinence (12 urge, 12 mixed)</td>
<td>Neocontrol system chair 20 min x 2 weekly for 8 weeks of 10Hz (urge incontinence group) or 10Hz for 10 min plus 50Hz for 10 minutes (mixed incontinence group)</td>
<td>Note was taken of previous PFM training, but the findings do not appear to have been taken into account in this study</td>
<td>Immediately after treatment, pad weight improved significantly in patients with urge incontinence, but not those with mixed incontinence. Subjective improvement was reported in 70% of all patients, and all patients showed significant improvement in some urodynamic measures.</td>
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<td>Yokoyama et al. 25</td>
<td>37 patients with incontinence (20 urge, 17 mixed)</td>
<td>20 mins x 2 weekly for 8 weeks</td>
<td>No reference to past or concurrent PFM training</td>
<td>Immediately after treatment, there was significant improvement in leak episodes, quality of life score, mean first desire to void (urge group), maximum cystometric volume (urge group), mean volume of involuntary detrusor contraction (urge group), 1 hour pad weight (stress group)</td>
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**Physiotherapy**

- **Dosage**
  - **Subjects**
    - 36 patients with incontinence following radical prostatectomy
    - 1 month (in electrical stimulation group), but NSD between groups at 6 months

- **Reference**
  - Yokoyama et al. 26
  - Culligan et al. 27

**Results**

- **Physiotherapy**
  - **Dosage**
    - **Subjects**
      - 51 multiparous women, 20-34 weeks’ gestation
      - 36 patients with incontinence following radical prostatectomy
    - **Reference**
      - Yokoyama et al. 26
      - Culligan et al. 27

**Table 1 continued**

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<tr>
<td>Yokoyama et al. 26</td>
<td>36 patients with incontinence following radical prostatectomy</td>
<td>Neocontrol system chair: 20 min x 2 weekly for 8 weeks</td>
<td>Physiotherapy exercises</td>
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<tr>
<td>Culligan et al. 27</td>
<td>51 multiparous women, 20-34 weeks’ gestation</td>
<td>Electrical stimulation: 50Hz x 10 min</td>
<td>Training and were checked for compliance (before start of intervention), at 4 weeks (post-intervention), at 14 weeks, 2 months (in Neocontrol system group), and 6 months (in electro stimulation group); 24-hour pad weight significantly improved at 1 month (in electrical stimulation group), but NSD between groups at 6 months</td>
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Requires the patient to regularly attempt maximum voluntary contractions between the (two) magnetic stimulation treatments.

If magnetic stimulation is to be used in any form to facilitate PFM contraction, it would seem optimum for the treatment to be under the supervision of a clinician experienced in the delivery and supervision of PFM exercise. It is also relevant that many patients can be trained sufficiently to self-administer electrically-enhanced PFM exercises in their home and in-between formal treatment sessions using one or other of the more simple TENS machines. This option is not available with the Neocontrol® system; although we note the recent development of Pulsegen, a device for home use, but as yet not extensively tested.

Given that the accepted dosage for strengthening exercises (high intensity – low repetition) is different to that for endurance (low intensity – high repetition), it follows that there should be a range of treatment dosages for TMNS – at least one directed at strength and another at endurance. It would also be desirable to be able to change the periods of contraction and relaxation as the patient’s voluntary control improves and tendency to fatigue diminishes. None of these details are adequately, if at all, covered by the Neocontrol® product in its present form.

Another aspect of PFM assessment and exercise concerns the synergy of pelvic floor with abdominal muscles, especially lower transversus abdominis, which provides for optimum defaecation, urination and defence against incontinence. This aspect of motor control training requires carefully-worded instructions to ensure correct muscle interactions and optimum functional use of the pelvic floor. Physiotherapists may facilitate such supervised synergistic exercise with the aid of electrical stimulation and or biofeedback. It would appear that these issues are not acknowledged or accepted by the advocates of TMNS.

The dosage for TMNS is controlled by a card inserted into the machine. While in theory many different cards could be prepared and purchased to accommodate different dosage needs, typically only one card is used, and purchase of others would likely be inconvenient, if not expensive. Again it needs acknowledgement that physiotherapists have full control of dosage when using percutaneous electrical stimulation apparatus.

While it might be argued that patients could have more than the usual two magnetic stimulation treatments per week in order to ensure optimum rate of strengthening or faster improvements in endurance or motor control, because the cards have a cost attached to every time they are used, more frequent TMNS treatments could be very expensive.
Clinical research findings

Another approach to evaluating the apparatus is to investigate the quality and results of published research focusing on use of TMNS treatment for the pelvic floor. As a relatively new treatment, most reported studies are published abstracts from conferences and therefore have limited detail and lack follow-up. Table 1 summarises the results of eight studies which in our estimation are well-presented. The studies summarised suggest that Neocontrol® treatment benefits patients in the short-term, but the benefit may be lost 6-12 months after treatment is discontinued.

Equally important, there has been little research comparing the benefits derived from magnetic stimulation with the results from voluntary exercise, with or without electrical stimulation or biofeedback. It is unclear in the reported studies whether or not the patients in these studies received PFM training from a physiotherapist before or during the period of the research.

In general, the number of subjects in each of the eight studies is not large, and the number of patients in subgroups when the patients are subdivided according to type of incontinence (urge, stress, mixed) is very low. There is also a lack of randomised controlled blinded trials, and a tendency to have a ‘one-dose-fits-all’ kind of incontinence approach. Hence, it is difficult to draw any firm conclusions about possible different benefits from magnetic stimulation with respect to the different types of incontinence.

Finally, it has been calculated by one supplier of the Neocontrol® system that its use to treat 100 patients can realise a profit of $68,000 per year. This profit is in part funded by Medicare (item nos 104, 105). By contrast, electrical stimulation used by physiotherapists in rooms is not charged for over and above the consultation fee. The authors of this paper believe that the current evidence for Neocontrol® system treatments does not justify these additional costs to the patient or health care system.

Conclusions

The theory and clinical evidence underpinning use of TMNS via the Neocontrol® system to strengthen PFM or increase endurance and at the dosages advocated does not correlate with current scientific evidence of skeletal muscle strengthening or other regimens of muscle exercise.

A search of the literature has shown that the clinical research undertaken into TMNS treatment has involved few patients.

It is concluded that the low number of participants in the study groups cannot provided meaningful statistical analysis or generalisations as to the efficacy of the treatment regimen.

In practical terms, magnetic stimulation seems to be more convenient for patients and therapists than exercise, electrical stimulation or biofeedback, and presents less risk of causing irritation or discomfort than electrical stimulation. On the other hand, it is expensive and less likely to be adequately prescriptive in treating the PFM without careful positioning and supervision of the patient. From clinical experience with exercise regimens, it seems inappropriate to use the same, or similar, dosage of TMNS on all disorders or all stages of progress of the same disorder.

The evidence suggests that magnetic stimulation is beneficial in the short-term, but the benefits may be lost after 6 or more months. Most importantly, there is no compelling evidence that magnetic field stimulation produces as great an effect, as sustained an effect, or as specific an effect, as that which can be achieved by exercise, with or without electrical stimulation or biofeedback.

However, a dearth of published papers and the lack of randomised clinical trials involving a large enough group to obtain statistically useful data emphasises the need for further research into this treatment of urinary incontinence; a conclusion which has also been drawn by Quek in her recent review of magnetic stimulation in the management of pelvic floor disorders 18. We therefore concur with Wilson et al. who stated: “At the moment there is not enough evidence for the efficacy of magnetic stimulation of women with urinary incontinence” 19[96].

References


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