ENAR -

PAIN RELIEF THAT'S FAST AND LASTS

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Introducing ENAR

The ENAR (Electro-Neuro-Adaptive-Regulator) is a Russian invention, a hand-held therapeutic device that is moved over the body to find and treat 'asymmetries' (disorders) through the skin. The ENAR uses reflex biofeedback, a dynamic computer-modulated interactive electro-stimulation, between itself and the soft tissue. By responding to physiological changes in the soft tissue the ENAR is able to effect the nervous system's natural adaptive functioning, the universal basis to all healing. As such, it is said that the ENAR can be used for the treatment of a very wide variety of painful syndromes.

Where did the ENAR come from? The ENAR technology was first developed in the 1970's as part of the Russian Space program where it was intended for use by Cosmonauts in outer space. Russian scientists have reported very promising anecdotal evidence to support its use, resulting in SC/ENAR therapy's popularity in Russia and Eastern Europe as an alternative to more conventional pain control and treatment strategies.

Sounds great, but does it work? A pilot study just completed by the Department of Health and Chiropractic at Macquarie University proves not only that ENAR works, but that it works faster than conventional TENS (Transcutaneous Electro Neuro Stimulation) treatment and that the benefits of treatment after active treatment has ceased is greater than for those treated by TENS.

TITLE: **A Pilot Study on the Effectiveness of ENAR Therapy on Chronic Neck Pain**
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Proving ENAR works

Setting up the pilot study

In order to prove the effects of treatment and longer-term outcome for patients treated by ENAR therapy are better than the conventional treatment (TENS), a randomised, single blinded controlled pilot study to compare the clinical effects of the ENAR with TENS for the treatment of non-complicated chronic neck pain within an Australian adult population was commissioned. Adults suffering from non-complicated chronic neck pain were recruited by advertising in two local newspapers in Sydney. The main inclusion criteria were uncomplicated chronic neck pain that had lasted for more than 6 weeks and no acute exacerbation in the 3 weeks prior to commencement of the trial.

Overall the study comprised two phases and lasted for 6 months. The first phase of the study assessed the effects of 20-minute treatments using a 12 visit treatment protocol over 6 weeks of ENAR, TENS or Placebo treatment. The second phase of the study assessed the longer-term outcome of the cohort using a variety of subjective and objective outcome measures.

Why study neck pain?

"Neck pain is second only to low back pain as the most common musculoskeletal disorder in population surveys and primary care, and, like low back pain, it poses a significant health and economic burden, being a frequent source of disability" Ferrari et. al 2003. Neck pain has a high disease burden:
One in four people already have, or will have, chronic neck pain.
These people will be twice as likely to be female than male.
The causes of chronic neck pain are not only physical.
Treatments are varied and effectiveness is inconclusive.
Cost of treating patients is increasing.

Treatment protocols and patients

Patients participating in the pilot study were randomly allocated into one of three treatment protocols: TENS treatment, ENAR treatment or a placebo (SHAM) treatment. This enabled the ENAR to be compared with both the standard treatment (TENS) and no treatment (SHAM). Any variation between the three treatment protocols at the beginning of the study can be attributed to random chance, while any variation at the end of the study could be assumed to be due the type of treatment therapy received by the patient. The treatment protocols and their sample size1 were:
ENAR (n=9) – these patients were treated with ENAR therapy.
TENS (n=7) – these patients were treated with the established TENS therapy.
SHAM (n=8) – these patients were treated using an inactive (switched off) ENAR unit lightly applied to the skin.

Phase 1 – initial regime, 12 treatments over 6 weeks,

On the first visit to the clinic each patient was randomised into one of the three treatment protocols. All patients were blinded to the treatment protocol they received. Patients received a total of 12 treatments, each lasting for 20 minute, as follows: 3 treatments per week in weeks 1 and 2, 2 treatments per week in weeks 3 and 4, and 1 treatment in weeks 5 and 6. At the beginning and end of each of these 12 treatments each patient was asked their current level of neck pain using a 10 point visual analogue scale (VAS) pain rating system.

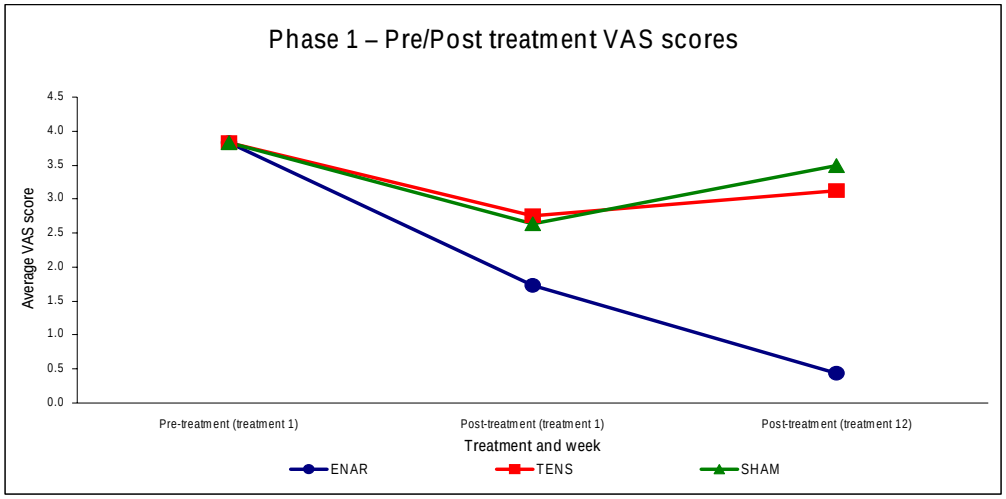
[1] 1) pre treatment (treatment 1) - average of all patients "prior" to randomisation (common starting point)
2) post treatment (treatment 1) **- average of each treatment protocol to show the benefit gained from just one treatment**
3) post treatment (treatment 12) - average of each treatment protocol to show the overall benefit gained over the 6 week period of 12 treatments.

Phase 2 – longer-term assessment outcome

Prior to and following the 12 treatments (Phase 1) patients were assessed every 6 weeks for a total period of 6 months (weeks 1, 6, 12, 18 and 24). At each assessment (conducted in person prior to treatment in weeks 1 and 6, and over the phone in weeks 12, 18 and 24) patients were instructed to complete a series of outcome measures in order to assess the longer-term effectiveness of the respective treatments for non-complicated chronic neck pain. The outcome measures used were:
subjective pain (using a visual analogue scale (VAS))
disability based questionnaire (the Neck Disability Index (NDI))
functionality based questionnaire (Patient Specific Functional Questionnaire (PSFS))
general health and quality of life (as using the SF-36 self report questionnaire)What was found – results from the pilot study

Phase 1 results

Change in pain relief VAS scores pre/post treatment



The Visual Analogue Scale (VAS) is a measure of pain intensity with 0 equivalent to no pain at all and 10 equivalent to the worst pain ever; the lower the VAS score the better the outcome. This graph gives the average VAS score prior to any treatment (pre-treatment week 1) and post-treatment for week 1 (initial treatment) and week 12 (final treatment), as measured by the treating clinician in training.

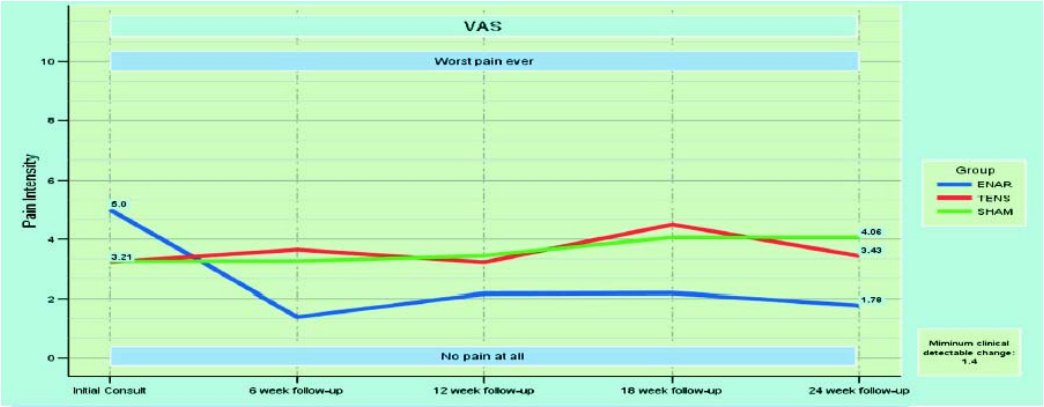
There was little difference in the pre and post VAS scores among those patients treated with SHAM, with little change between treatment 1 and 12. Treatment with TENS had a reduction in pain intensity greater than that of the SHAM treatment protocol, with a slight decline in scores over the 12 treatments.

Even after the initial treatment there was a much greater reduction in pain among those treated by ENAR. After the six week course of 12 treatments patients treated with ENAR experienced a reduction in pain intensity much greater than that experienced by those treated by either TENS or SHAM, with an overall decline in the VAS score over the treatment period. The large VAS score reduction among those treated by ENAR is considered to be clinically significant.

The ENAR treatment therapy was successful in significantly reducing the intensity of chronic neck pain among the patients treated when compared to either the TENS or SHAM treatment protocols both immediately following treatment as well as over the course of 12 treatments.

Phase 2 results

Change in pain relief VAS scores after six months



This graph gives the average VAS score for each treatment protocol at each of five time points as measured by the treating clinician.

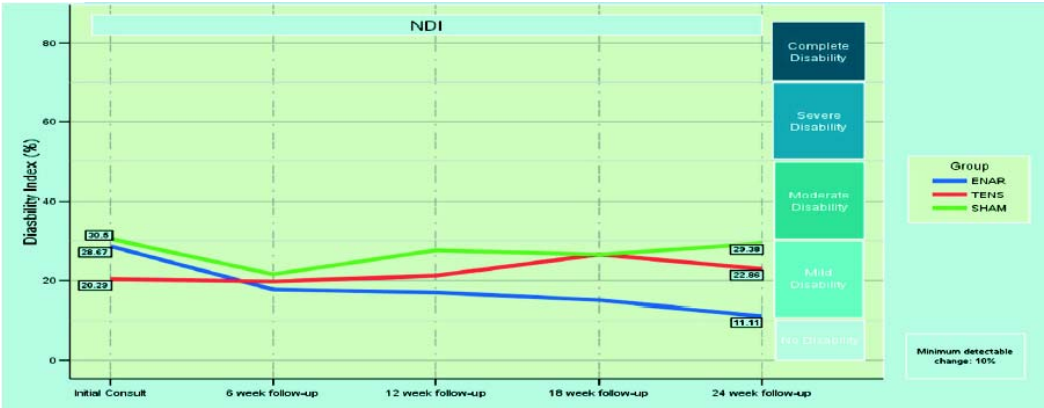
As might be expected SHAM patients showed no change during the treatment period and deteriorated slowly but steadily over time, from an initial and week 6 VAS score of 3.3 to VAS score of 4.1 at week 24. Among the 8 SHAM patients 2 didn't improve, 3 improved and 3 deteriorated between their initial VAS score and their week 24 VAS score.

Similarly, and perhaps unexpectedly, the TENS patients deteriorated slightly during treatment and over the course of the study (initial VAS=3.2, week 6 VAS=3.6, week 24 VAS=3.4). Post treatment the VAS scores for patients receiving TENS treatment varied between 3.21 at week 12 to a high of 4.50 at week 18. Among the 7 TENS patients 1 didn't improve, 2 improved and 4 deteriorated between their initial VAS score and their week 24 VAS score.

Patients in the ENAR treatment protocol had a much greater reduction in the VAS scores during treatment (initial=5.00, week 6=1.4) than was seen for either the TENS or SHAM treatment protocols. This reduction may appear more dramatic due to the only participant scoring a 10 on their initial VAS score being in this treatment protocol. However, even if the average initial VAS score for ENAR was changed to match the TENS and SHAM treatment protocols, the decline during treatment is still much greater. Although ENAR patients declined slightly post treatment (week 6=1.4, week 24=1.8), the VAS scores were less variable than for TENS, and were consistently lower than the two other treatment protocols. Among the 9 ENAR patients 7 improved and 2 deteriorated between their initial VAS score and their week 24 VAS score.

Both the TENS and SHAM treatment protocols suggest that any improvement in the VAS score occurs only during treatment and is not sustained post treatment. Conversely, the ENAR therapy showed a much greater improvement during treatment, and sustained this improvement through to week 24. Based on this pilot study it appears that the ENAR is a more efficient treatment than TENS or SHAM in both the reduction of pain during treatment and for maintaining reduced pain levels after treatment for those suffering chronic neck pain.

Change in neck disability index scores after six months



The Neck Disability Index (NDI) questionnaire is a measure of neck disability with 0 equivalent to no disability and 50 equivalent to complete disability; the lower the NDI score the better the outcome. This graph gives the average NDI score for each treatment protocol at each of five time points as measured by a clinician.

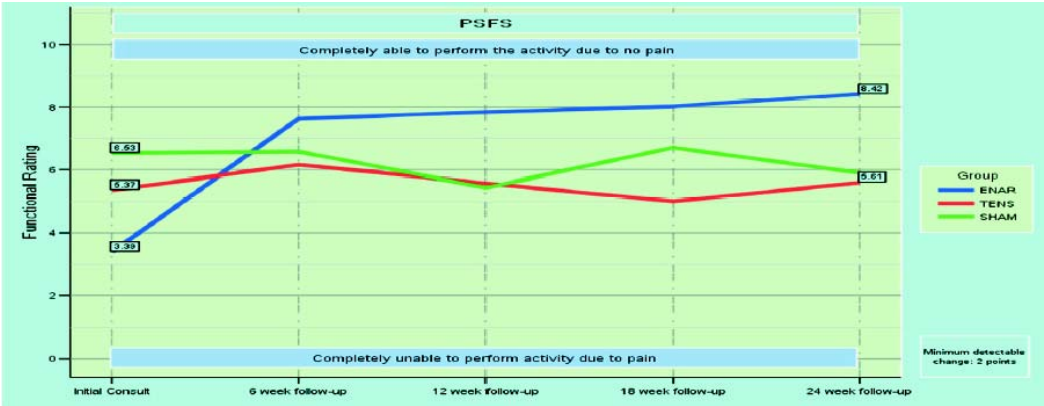
Patients in the SHAM treatment protocol declined during the treatment period but then deteriorated slowly and steadily over the course of the study period back to near their initial score (initial NDI=30.5, week 6 NDI=21.5, week 24 NDI=29.4). Among the 8 patients of the SHAM treatment protocol 4 improved and 4 deteriorated between their initial NDI score and their week 24 NDI score.

By chance the TENS treatment appear to have much lower NDI scores at the commencement of this study than either the SHAM or ENAR treatment protocols; by week 6 all treatments had similar NDI scores. As such, there was little change during the treatment period for the TENS treatment protocol, and over the course of the study patients tended to deteriorate slightly (initial NDI=20.3, week 6 NDI=19.7, week 24 NDI=22.9). Post treatment NDI scores in the TENS treatment protocol were highest at week 18 (26.6). Among the 7 patients of the TENS treatment protocol 3 improved and 4 deteriorated between their initial NDI score and their week 24 NDI score.

ENAR patients had the greatest reduction in NDI scores during treatment (initial=28.7, week 6=17.7) than was seen for either the TENS or SHAM treatment protocols. This reduction continued at each time point post treatment (week 12=16.9, week 18=15.0, week 24=11.1), and were consistently lower than the two other treatment protocols. Among the 9 ENAR patients all improved (had lower NDI scores) between their initial NDI score and their week 24 NDI score.

Post treatment both the TENS and SHAM treatment protocols suggest that any improvement in the NDI score gained during treatment is not sustainable. Conversely, the ENAR showed a much greater decline in the NDI score during treatment, with the NDI score continuing to decline through to week 24. Based on this pilot study it appears the ENAR is a more efficient treatment than TENS or SHAM in both the reduction of neck disability during and post treatment for those suffering chronic neck pain.

Change in patient specific functional scores after six months



The Patient Specific Functional (PSF) score is a measure of the patients ability to function without pain in activities that are normally affected by their neck pain (up to five activities can be selected). For the PFS the inability to function due to neck pain is scored 0 while the ability to function without neck pain is scored 10 (higher the score the better). This graph gives the average PSF score for each treatment protocol at each of five time points as measured by a clinician.

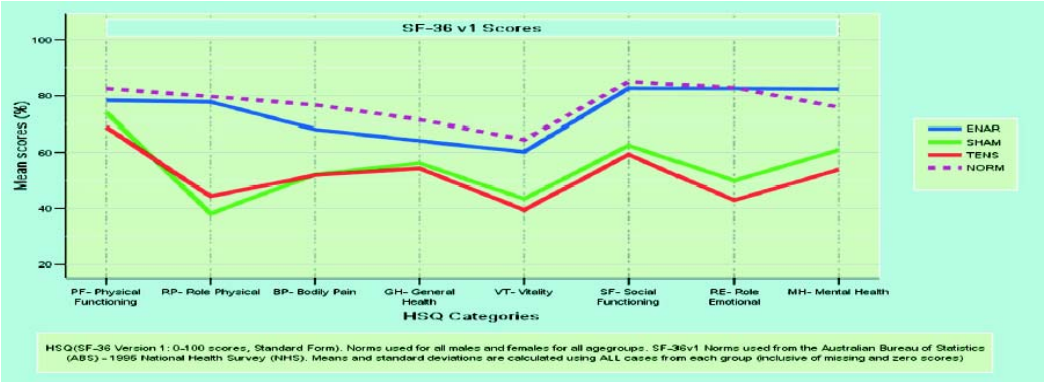
During the treatment period the patients in the SHAM treatment protocol were unchanged, but declined slightly over the course of the study (initial PSF=6.5, week 6 PSF=6.6, week 24 PSF=5.9). Among the 8 SHAM patients 5 improved and 3 deteriorated between their initial PSF score and their week 24 PSF score.

The TENS treatment protocol improved slightly during the treatment period but due to a decline post treatment over the course of the study patients were unchanged (initial PSF=5.4, week 6 PSF=6.2, week 24 PSF=5.6). TENS post treatment PSF scores were lowest at week 18 (5.0). Among the 7 TENS patients 3 improved and 4 deteriorated between their initial PSF score and their week 24 PSF score.

Although ENAR patients had the lowest PSF score at the commencement of this study, by week 6 they had the highest PSF scores (initial=3.4, week 6=7.6) compared to TENS and SHAM. From week 6 patients treated by ENAR had consistently higher PSF scores than the two treatment protocols, with the PSF score increasing at each time point post treatment (week 12=7.8, week 18=8.0, week 24=8.4). Among the 9 ENAR patients all improved (had higher PSF scores) between their initial PSF score and their week 24 PSF score.

Post treatment both the TENS and SHAM treatment protocols suggest that any improvement in the PSF score gained during treatment is not sustainable. Conversely, ENAR showed a much greater increase in the PSF score during treatment, with the PSF score continuing to increase through to week 24. Based on this pilot study it appears that ENAR is a more efficient treatment than TENS or SHAM for its ability to improve function without neck pain both during and post treatment for those suffering chronic neck pain.

Comparison of general health scores at six months



The Short Form 36 (SF-36) Health Inventory questionnaire is a validated psychometric tool comprised of 36 questions which can be reduced to 8 scales measuring: physical functioning (PF), role–physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role–emotional (RE) and mental health (MH). These eight scales can be further reduced to two standardised indexes (mean 50, st.dev 10): physical (PCS) and mental (MCS). The higher the score on any of the eight scales or two indexes the better. These analyses do not take account of age, which may be influential on the result.

This graph gives the average SF-36 score for each treatment protocol at the end of the pilot study for each of the eight scales, as measured by a clinician. Also indicated on this graph for further comparison is the average score for the Australian population (NORM), as determined by the 1995 ABS National Health Survey.

On all scales (PF, RP, BP, GH, VT, SF, RE and MH) ENAR had the highest scores, and was just below, or in the case of mental health (MH) just above, the Australian norm. The TENS and SHAM treatment protocols were significantly below the Australian norm for all scales.

Considering the physical index (PCS) there was little difference between the three treatment protocols, with all being below the standardised norm of 50. The TENS treatment protocol was slightly lower than SHAM in the mental index (MCS), both of which are significantly below the standardised norm of 50; ENAR is a little above the norm.

Based on this pilot study it appears that the patients treated by ENAR therapy enjoy better health than patients treated by either TENS or SHAM.

What does all this mean

Summary of pilot study findings

ENAR has been successful in.....

- Providing both short & long term reductions in neck pain intensity.
- Providing short & long term improvement in patient specific function.
- Causing clinically observable reductions in neck disability.
- Providing both short and long term improvements in both physical and psychological parameters.

Despite low power (VAS (0.156), NDI (0.255) PFSF (0.211)) the study authors were still able to successfully demonstrate clinically significant trends in reducing the signs and symptoms associated with non complicated neck pain in patients receiving ENAR therapy compared to both TENS and SHAM therapies. Further studies with higher power (larger cohort of patients) should be able to statistically prove these clinically significant findings.

This promising outcome indicates a need for further, larger trials of ENAR to more accurately determine the degree of benefit, exact clinical role and breadth of clinical application of this potential new modality for the treatment of chronic pain.

SO, IN BROAD SUMMARY...

There is no doubt ENAR works. ENAR is found to be a cost-effective, long lasting treatment for chronic neck pain. The pilot study discussed here however is the first Western university randomised control trial of this type of therapy/technology. It does demonstrate the effectiveness of ENAR for both short term and long term pain relief and for functional and general health improvement.

ENAR can be now further studied and hopefully used successfully for the treatment of a wide variety of painful dysfunctions, as is reported in Russia. The ENAR's ability to find and treat 'asymmetries', as the Russians call them, through the skin is an innovative and potent new way to treat disorder directly, by prompting the body to heal itself. This approach recognises the opportunity not only to relieve painful dysfunction but also to help generate optimal condition and good health.

In summary, ENAR is an emerging and promising, non-invasive and non toxic, treatment option that lies within reach of both professional health practitioners and personal home users. There is a fast growing list of Western anecdotal case reports that suggest it might well be a quantum leap forward in therapy. Time will tell how much more the ENAR is capable of achieving.

ENAR™ Therapy System